Lunsumio®
mosunetuzumab-axgb
injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™
mosunetuzumab-axgb
subcutaneous injection **5 mg | 45 mg**

Impressive patient responses from the first fixed-duration bispecific antibody for 3L+ FL[1]

80% (n=72/90) of patients treated with LUNSUMIO® [IV] achieved an overall response (95% CI: 70%-88%)[1]

*LUNSUMIO VELO™ is available as a quick, ~1 minute, subcutaneous injection[2]**

*Refers to the injection time and does not include other aspects of treatment; actual clinical time may vary.[2]

NCCN CATEGORY 2A PREFERRED

National Comprehensive Cancer Network® (NCCN®) recommends mosunetuzumab-axgb (LUNSUMIO) as a Category 2A preferred treatment option after at least two prior systemic therapies for patients with relapsed or refractory follicular lymphoma.[3]

Indication

LUNSUMIO (mosunetuzumab-axgb) or LUNSUMIO VELO is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

BOXED WARNING

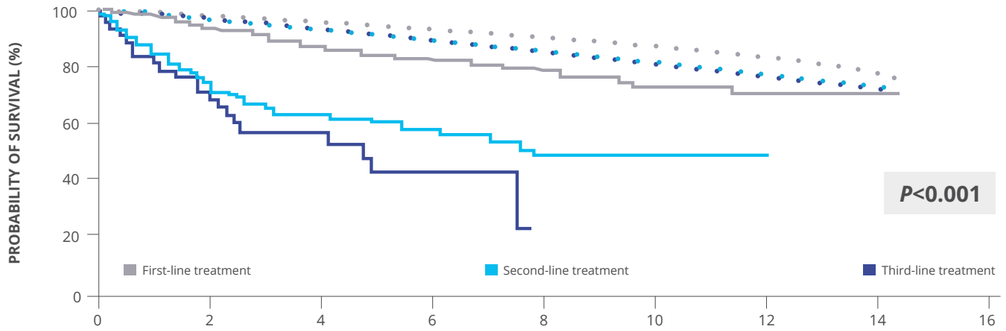
Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO or LUNSUMIO VELO. Initiate treatment with the LUNSUMIO or LUNSUMIO VELO step-up dosing schedule to reduce the risk of CRS. Withhold LUNSUMIO or LUNSUMIO VELO until CRS resolves or permanently discontinue based on severity.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Historically unmet need: patients with FL experience worse outcomes with each line of treatment[4]*

FL has been characterized by a pattern of remission and relapse, and survival rates have been shown to decrease with each line of treatment

Historical overall survival by line of treatment in FL



PTS AT RISK									
FIRST-LINE TREATMENT	348	294	220	157	106	54	21	3	0
SECOND-LINE TREATMENT	111	62	45	35	14	8	0	0	0
THIRD-LINE TREATMENT	41	25	12	6	0	0	0	0	0

Overall survival (solid line) of FL patients in first-, second-, and third-line treatment and expected survival (dotted line) of an age- and sex-matched, non-FL Spanish population.

Because of this unmet need, additional mechanisms are important to consider when treating 3L+ FL

*In a study of 348 patients newly diagnosed with FL in 2 institutions between 2001 and 2014 who received chemoimmunotherapy.

Important Safety Information (cont'd)

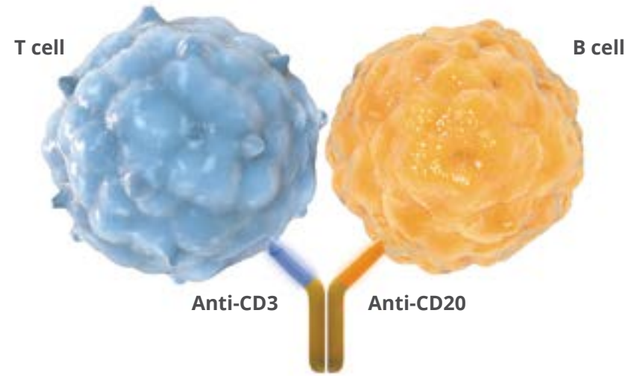
BOXED WARNING: Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO or LUNSUMIO VELO. Additional warnings and precautions include neurologic toxicity including immune effector cell-associated neurotoxicity syndrome, infections, hemophagocytic lymphohistiocytosis, cytopenias, tumor flare, risk of medication errors with incorrect product use, and embryo-fetal toxicity.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

LUNSUMIO® [IV] and LUNSUMIO VELO™ are T-cell engaging bispecific antibodies for 3L+ FL[1,2]

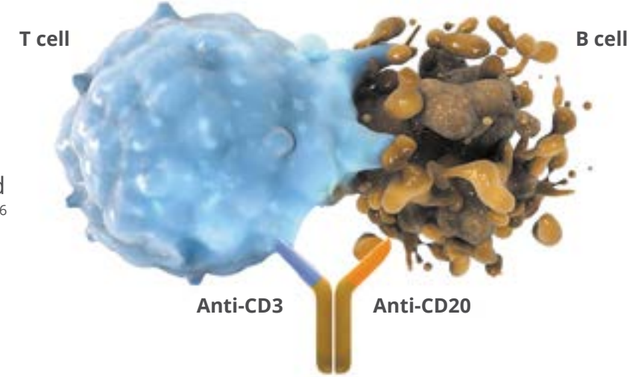
Capture and connect

Mosunetuzumab-axgb is designed to bind to **CD20** on B cells and **CD3** on cytotoxic T cells.[1,2,5]



Direct to destroy

When both arms of mosunetuzumab-axgb are engaged, the T cell is activated and directed to kill the bound B cell.[1,2,5,6]



Important Safety Information (cont'd)

Warnings and Precautions

Cytokine Release Syndrome (CRS)

LUNSUMIO or LUNSUMIO VELO can cause CRS, including serious or life-threatening reactions.

CRS occurred in 39% of patients who received LUNSUMIO at the recommended dosage in the clinical trial (N=218), with Grade 1 CRS occurring in 28%, Grade 2 in 15%, Grade 3 in 2%, and Grade 4 in 0.5% of patients. Among 86 patients who experienced CRS, CRS recurred in 28%. Most cases of CRS occurred following doses of 1 mg on Cycle 1 Day 1 (15%), 2 mg on Cycle 1 Day 8 (5%), and 60 mg on Cycle 1 Day 15 (33%). Five percent of patients experienced CRS after receiving 60 mg on Cycle 2 Day 1 with 1% of patients experiencing CRS following subsequent doses of LUNSUMIO.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO®: the first FDA-approved fixed-duration bispecific antibody for 3L+ FL[1]

In GO29781, an open-label, non-randomized, multicenter, multi-cohort Phase 2 study, LUNSUMIO was administered for 8 or 17, 21-day treatment cycles[1,7]

Eligibility[1,7]

- **Histologically confirmed diagnosis of FL (Grade 1, 2, or 3a)**
- **≥2 prior therapies, including:**
  - Anti-CD20 antibody
  - Alkylator

Patient cohorts[1]

Efficacy subset

Pivotal cohort (n=90)

Safety

Pooled safety population (N=218)*

Endpoints[1,7]

Primary endpoint

- IRF-assessed CR rate

Secondary endpoints:

- ORR
- DOR
- DOCR

Safety

- Efficacy pivotal cohort (n=90) is a subset of the pooled safety population (N=218)

- Patients received LUNSUMIO with step-up doses of 1 mg on Cycle 1 Day 1 and 2 mg on Cycle 1 Day 8, followed by 60 mg on Cycle 1 Day 15, and 60 mg on Cycle 2 Day 1, then 30 mg every 3 weeks in subsequent cycles[1]
- 8 total cycles (~6 months) if CR was achieved[1†]
- 17 total cycles (~12 months) if PR/SD was achieved after 8 cycles[1†]

*Multi-cohort study in hematologic malignancies.[1]
†Unless patients experienced progressive disease or unacceptable toxicity.[1]

Important Safety Information (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

The median time to onset of CRS from the start of administration of LUNSUMIO in Cycle 1 Day 1 was 5 hours (range: 1 hour to 3 days), Cycle 1 Day 8 was 28 hours (range: 5 hours to 3 days), Cycle 1 Day 15 was 25 hours (range: 0.1 hours to 16 days), and Cycle 2 Day 1 was 46 hours (range: 12 hours to 3 days). The median duration of CRS was 3 days (range: 1 to 29 days).

Clinical signs and symptoms of CRS occurring in patients receiving LUNSUMIO included, but were not limited to, fever, chills, hypotension, tachycardia, hypoxia, and headache. Concurrent neurologic adverse reactions occurred in 6% of patients and included, but were not limited to, headache, confusional state, and anxiety.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO™ full Prescribing Information.

IV INFUSION

LUNSUMIO was studied in a heavily pretreated, highly refractory patient population (n=90)[1,7]

Baseline characteristics

Prior cancer therapy regimen	Prior auto-SCT	**21%**
	Prior CAR-T	**3%**
	Prior rituximab plus lenalidomide	**9%**
Relapsed/refractory status	Refractory to last prior therapy	**69%**
	Refractory to any prior anti-CD20	**79%**
	Double refractory to prior anti-CD20 and alkylator	**53%**

Other select baseline characteristics

60 years Median age (range: 29-90)	**52%** POD24	**100%** ECOG PS of 0-1
44% FLIPI ≥3	**77%** Ann Arbor stage ≥3	**34%** Bulky disease >6 cm

Important Safety Information (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

CRS occurred in 30% of patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial (N=94), with Grade 1 CRS occurring in 20%, Grade 2 in 7%, and Grade 3 in 2.1%. Among 28 patients who experienced CRS, CRS recurred in 14% of patients. CRS occurred most commonly after the first two doses: 19% of patients experienced CRS after the Cycle 1 Day 1 dose, 13% after the Cycle 1 Day 8 dose, and 2.1% after the Cycle 1 Day 15 dose.

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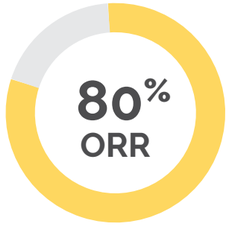
Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

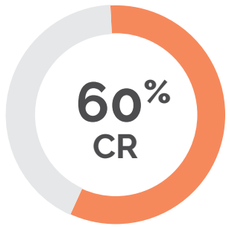
Impressive response rates achieved in difficult-to-treat patients[1,7]



of patients achieved an overall response[1]
(n=72/90; 95% CI: 70%-88%)

- 20% PR (95% CI: 12%-30%)

Rapid, 1.4-month median time to response (range: 1.1-8.9 months).[1]



of patients achieved a complete response[1]
(n=54/90; 95% CI: 49%-70%)

3.0-month median time to complete response (range: 1.1-18.9 months).[7,8]

Majority of patients achieved a complete response with LUNSUMIO® (n=54/90)[1]

Important Safety Information (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

The median time to CRS onset from the start of LUNSUMIO VELO administration was 17 hours (range: 7 to 33 hours) with the Cycle 1 Day 1 dose, and 62 hours (range: 30 to 113 hours) with the Cycle 1 Day 8 dose. CRS resolved in all patients, after a median duration of 2 days (range: 1 to 15 days).

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO™ full Prescribing Information.

IV INFUSION

Patients experienced durable remission with this fixed-duration therapy[1,7]

mDOR was 23 months in patients who achieved an overall response[1*†]
(95% CI: 10-NR)

~6 out of 10 patients who achieved an overall response maintained response at 18 months.[1,7†]

mDOCR was not reached in patients who achieved a complete response[7†‡]
(95% CI: 14.6-NR)

~6 out of 10 patients who achieved complete response maintained complete response at 18 months.[7†]

The median follow-up for DOR was 14.9 months.[1]

*From the initial occurrence of the documented PR or CR until disease progression or death due to any cause.[1]
†Kaplan-Meier estimate.[1,7]
‡From the initial occurrence of the documented CR until disease progression or death due to any cause.[7]

Important Safety Information (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

Clinical signs and symptoms of CRS occurring in patients receiving LUNSUMIO VELO included fever, hypoxia, chills, tachycardia, and headache. Concurrent neurologic adverse reactions occurred in 5% of patients and included but were not limited to headache, dizziness, lethargy, memory impairment, and peripheral neuropathy.

Initiate therapy according to LUNSUMIO or LUNSUMIO VELO step-up dosing schedule to reduce the risk of CRS. Administer pretreatment medications to reduce the risk of CRS, ensure adequate hydration, and monitor patients following administration of LUNSUMIO or LUNSUMIO VELO accordingly.

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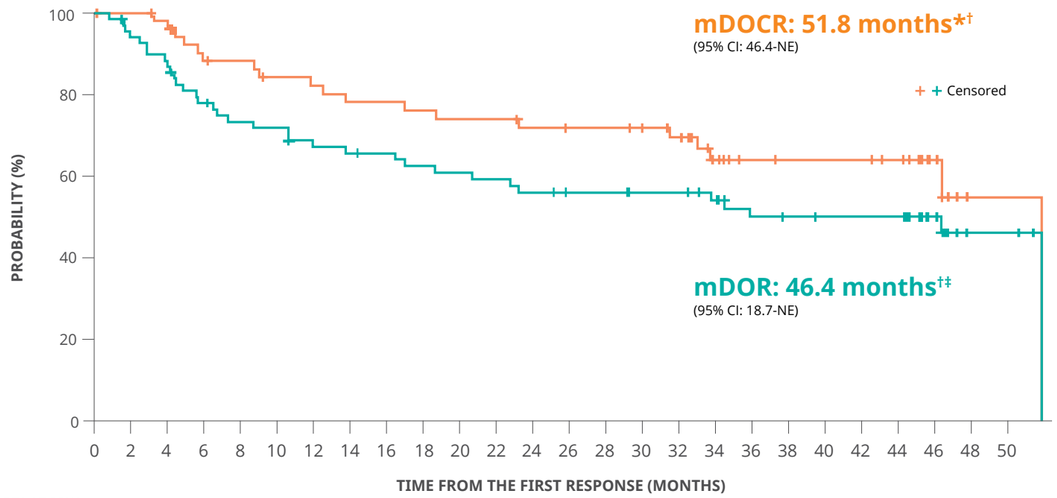
Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

Four-year, long-term follow-up data: duration of response[9]

Limitations: no inference may be drawn as the data are from exploratory follow-up analyses. The median statistics were estimated at the tail portion of the Kaplan-Meier curve where the small number of available patients at risk may affect reliability of the data.



PTS AT RISK

CR	54	53	50	45	44	41	40	38	38	37	36	36	34	33	33	31	29	22	18	17	17	17	15	8	1	1
OR	70	65	60	52	48	47	43	42	41	39	38	37	35	33	33	32	32	29	24	23	22	22	22	14	3	3

The estimated median follow-up for the long-term analysis was 49.4 months[9§]

*From the initial occurrence of the documented CR until disease progression or death due to any cause.[7]
†Responders per investigator assessment.[9]
‡From the initial occurrence of the documented PR or CR until disease progression or death due to any cause.[1]
§Data cutoff was May 13, 2024.[9]

Important Safety Information (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care; withhold or permanently discontinue LUNSUMIO or LUNSUMIO VELO based on severity.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO™ full Prescribing Information.

IV INFUSION

Consistent treatment responses demonstrated across a range of difficult-to-treat patients[7]

LUNSUMIO® was studied across patient subgroups, including refractory status, prior treatment, bulky disease, FLIPI risk factors, and mutations

Limitations: these post hoc analyses were exploratory and no formal inference may be drawn.

Response rates by select subgroups

Subgroup	ORR	CR
FLIPI ≥3 (n=40)	**83%**	**60%**
Bulky disease (n=31)	**74%**	**61%**
Refractory to last prior therapy (n=62)	**77%**	**52%**
Refractory to any prior anti-CD20 therapy (n=71)	**77%**	**55%**
Refractory to any prior anti-CD20 therapy and an alkylating agent (double refractory) (n=48)	**71%**	**50%**
Refractory to any prior PI3K inhibitor (n=12)	**75%**	**50%**
Prior rituximab-lenalidomide therapy (n=8)	**75%**	**25%**
Prior CAR T-cell therapy (n=3)	**100%**	**33%**
POD24 (n=47)	**85%**	**57%**
EZH2 mutation (n=8)	**75%**	**38%**

Important Safety Information (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO® [IV] and LUNSUMIO VELO™: shared features across different administration routes[1,2,7]

Shared features of LUNSUMIO [IV] and LUNSUMIO VELO

- **Fixed-duration** therapy[1,2]
- **Off-the-shelf** availability[1,2,7]
- Can be administered at **outpatient centers**, including **local infusion centers**[1,2,7]
- **No hospitalization required** at initiation of treatment[1,2]
  - Hospitalization may be needed to manage select AEs and should be considered for subsequent infusions or injections following a Grade 2 CRS event. Hospitalization is recommended for subsequent infusions or injections following a Grade 3 CRS event
- **Single-dose**, ready-to-use vials with no reconstitution required[1,2]*
- **Same J-code**

Do not substitute LUNSUMIO VELO for or with LUNSUMIO [IV].[1,2]

*LUNSUMIO [IV] and LUNSUMIO VELO come in different vial configurations and concentrations. Additional preparation steps are required.[1,2] See pages 20-23 for preparation steps.

Important Safety Information (cont'd)

Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

LUNSUMIO or LUNSUMIO VELO can cause serious and life-threatening neurologic toxicity, including ICANS.

Neurologic toxicity occurred in 39% of patients who received LUNSUMIO at the recommended dosage in the clinical trial, with Grade 3 neurologic toxicity occurring in 3% of patients. The most frequent neurologic toxicities were headache (21%), peripheral neuropathy (13%), dizziness (11%), and mental status changes (6%, including confusional state, disturbance in attention, cognitive disorder, delirium, encephalopathy, and somnolence). ICANS was reported in 1% of patients (Grade 1: 0.5%, Grade 2: 0.5%) who received LUNSUMIO at the recommended dosage in the clinical trial.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

LUNSUMIO VELO—a faster way to administer treatment vs LUNSUMIO [IV][1,2†]

Unique features of LUNSUMIO VELO

- **Quick administration:** LUNSUMIO VELO can be administered in ~1 minute[2‡]
- Get to **target dose** faster[1,2]
- All premedications can be **given orally**[2]
- **After Cycle 1, all premedications are optional**, including corticosteroids[2§]
  [§]Premedications may be required past Cycle 1 to reduce the risk of CRS and injection-site reactions. See page 17 for recommended premedications.
- **Hyaluronidase-free** formulation[2]

LUNSUMIO VELO is a fixed-duration treatment and is given in ~1 minute[2‡]

[†]This resource pertains only to differences in dosing and administration.
[‡]Refers to the injection time and does not include other aspects of treatment; actual clinical time may vary.[2]

Important Safety Information (cont'd)

Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (cont'd)

Neurologic toxicity occurred in 53% of patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial, with Grade 3 neurologic toxicity occurring in 1.1% of patients. The most frequent neurologic toxicities were headache (17%), insomnia (15%), dizziness (10%), and mental status changes (7%, including confusion and lethargy). ICANS or suspected ICANS was reported in 3.1% of patients (all Grade 1) who received LUNSUMIO VELO at the recommended dosage in the clinical trial.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO VELO™ was evaluated in a dose-expansion cohort of GO29781[2,10]

GO29781: An open-label, non-randomized, multicenter, multi-cohort Phase 2 study

Eligibility

- **Histologically confirmed diagnosis of FL (Grade 1, 2, or 3a)**
- **≥2 prior therapies, including:**
  - Anti-CD20 antibody
  - Alkylator

N=94

Endpoints

Efficacy:

- ORR
- DOR
- CR rate
- DOCR

Safety

- Patients received LUNSUMIO VELO with step-up doses of 5 mg on Cycle 1 Day 1, 45 mg on Cycle 1 Day 8, 45 mg on Cycle 1 Day 15, then 45 mg every 3 weeks in subsequent cycles[2]
- 8 total cycles (~6 months) if CR was achieved[2]*
- 17 total cycles (~12 months) if PR/SD was achieved after 8 cycles[2]*

LUNSUMIO VELO was also studied in a heavily pretreated, highly refractory patient population (N=94)[2]

Prior cancer therapy regimen	Prior auto-SCT	**20%**
	Prior CAR-T	**4%**
	Prior rituximab plus lenalidomide	**16%**
	Prior anti-CD20 and alkylator	**100%**
Relapsed/refractory status	Refractory to prior anti-CD20	**67%**
	Double refractory to prior anti-CD20 and alkylator	**46%**
	POD24	**44%**

*Unless patients experienced progressive disease or unacceptable toxicity.[2]

Important Safety Information (cont'd)

Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (cont'd)

Across a broader clinical trial population, ICANS or suspected ICANS occurred in 2.2% (21/949) of patients who received LUNSUMIO or LUNSUMIO VELO. The most frequent manifestations included confusional state and lethargy. Twenty patients had Grade 1-2 events and 1 patient had a Grade 3 event. The majority of cases (75%) occurred during the first cycle of treatment. The median time to onset was 17 days (range: 1 to 48 days). In total, 88% of cases resolved after a median duration of 3 days (range: 1 to 20 days).

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Results with LUNSUMIO VELO[2,11]

75% ORR

of patients achieved an overall response[2]
(n=70/94; 95% CI: 64%-83%)
- 16% PR (95% CI: 9%-25%)

- **Median duration of response: 22 months** (95% CI: 17-23)[†‡]
- 7 out of 10 patients who achieved an overall response maintained response at 12 months (70%; 95% CI: 59%-81%)[†]
- 6 out of 10 patients who achieved an overall response maintained response at 18 months (60%; 95% CI: 46%-73%)[†]

59% CR

of patients achieved a complete response[2,11]
(n=55/94; 95% CI: 48%-69%)

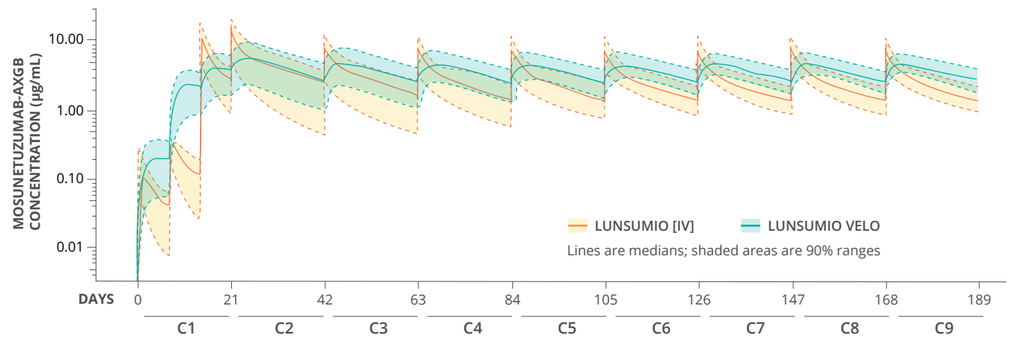
- **Median duration of complete response: 21 months** (95% CI: 19–NE)[†§]
- ~7 out of 10 patients who achieved a complete response maintained the complete response at 12 months (72%; 95% CI: 60%-85%)[†]

The median follow-up for DOR was 16 months.[2]

PK exposures of LUNSUMIO VELO and LUNSUMIO® [IV][2,10]

The subcutaneous to intravenous GMR was 1.39 (90% CI: 1.20-1.61) for $C_{trough(C3)}$ and 1.06 (90% CI: 0.92–1.21) for AUC_{0-84}

Predicted LUNSUMIO [IV] and LUNSUMIO VELO concentrations over time



- Observed Cycle 3 serum trough concentration was the lowest drug concentration before the next dose (ie, pre-Cycle 4 dose)[2,10,11]
- AUC_{0-84} represents the total drug exposure over the first 84 days of treatment, capturing exposure during both the step-up dosing phase and the maintenance dosing phase[2,10,11]

[†]Kaplan-Meier estimate.[2]
[‡]From the initial occurrence of the documented PR or CR until disease progression or death due to any cause.[2]
[§]From the initial occurrence of the documented CR until disease progression or death due to any cause.[11]

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Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection **5 mg | 45 mg**

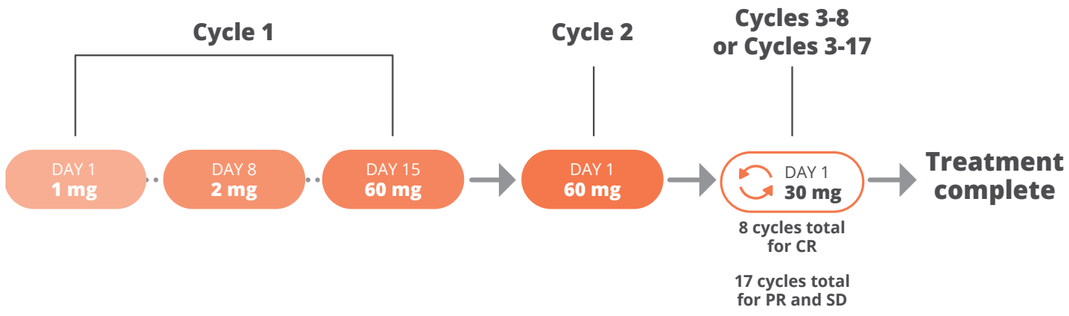
Subcutaneous study des

IV INFUSION SUBQ INJECTION

LUNSUMIO® [IV] is the first fixed-duration bispecific antibody for 3L+ FL[1]

Treatment can be completed in as little as 6 months—or 8, 21-day cycles*—without hospitalization at treatment initiation†

Recommended dosing schedule for LUNSUMIO [IV]



For Cycle 1: Administer infusion over a minimum of 4 hours

For Cycles 2 and 3+: Administer over 2 hours if infusions from Cycle 1 were well-tolerated

Treatment duration for LUNSUMIO [IV] and LUNSUMIO VELO™ depends on patient response[1,2]

- 8 cycles (~6 months) for patients who achieve a CR*
- 17 cycles (~12 months) for patients who achieve a PR or have SD after 8 cycles*

Important dosing information for LUNSUMIO [IV] and LUNSUMIO VELO[1,2]

- LUNSUMIO VELO and LUNSUMIO [IV] have different dosage and administration instructions
  - LUNSUMIO VELO is for subcutaneous use only
  - LUNSUMIO [IV] is for intravenous use only
  - Check the product label to ensure that the correct formulation (LUNSUMIO VELO or LUNSUMIO [IV]) is being prescribed and administered
  - Do not substitute LUNSUMIO VELO for or with LUNSUMIO [IV] and vice versa
- Administer LUNSUMIO [IV] and LUNSUMIO VELO to well-hydrated patients
- Premedicate before each dose in Cycle 1 for LUNSUMIO [IV] and LUNSUMIO VELO and Cycle 2 for LUNSUMIO [IV]
- LUNSUMIO [IV] and LUNSUMIO VELO should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as cytokine release syndrome and neurologic toxicity, including ICANS

*Unless there is disease progression or unacceptable toxicity.[1,2]
†Hospitalization may be needed to manage select AEs in some patients.[1,2]

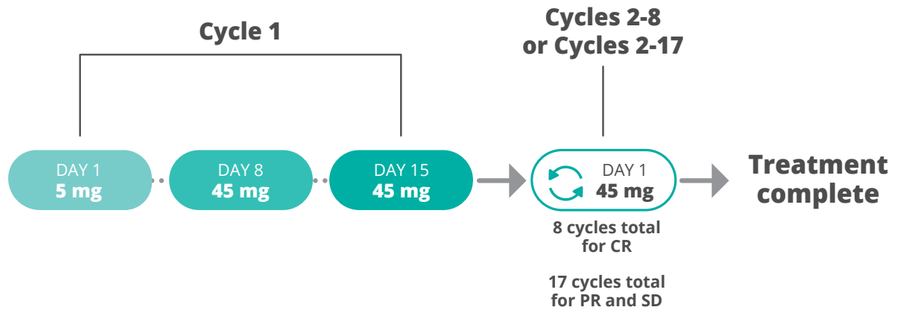
Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

IV INFUSION SUBQ INJECTION

LUNSUMIO VELO: same fixed-duration schedule as LUNSUMIO [IV][1,2]

LUNSUMIO VELO is given for the same total number of cycles as LUNSUMIO [IV] and without hospitalization at treatment initiation‡

Recommended dosing schedule for LUNSUMIO VELO[2]



For all cycles administer subcutaneously over ~30 seconds to 1 minute

LUNSUMIO VELO: get to target dose in Cycle 1[2]

‡Hospitalization may be needed to manage select AEs in some patients.[2]

Important Safety Information (cont'd)

Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (cont'd)

Coadministration of LUNSUMIO or LUNSUMIO VELO with other products that cause dizziness or mental status changes may increase the risk of neurologic toxicity.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient, consider neurology evaluation as appropriate, and provide supportive therapy based on severity; withhold or permanently discontinue LUNSUMIO or LUNSUMIO VELO based on severity and follow management recommendations.

Patients who experience neurologic toxicity such as tremors, dizziness, insomnia, severe neurotoxicity, or any other adverse reactions that impair consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

Recommended premedications for LUNSUMIO® [IV][1]

The following premedications are recommended before LUNSUMIO [IV] infusion begins to reduce the risk of CRS and infusion-related reactions

Premedication to be administered prior to LUNSUMIO [IV] infusion

Treatment cycle	Patients requiring premedication	Premedication	Dosage	Administration
Cycle 1 and Cycle 2	All patients	Corticosteroid	Dexamethasone 20 mg (preferred) IV or methylprednisolone 80 mg IV	Complete at least 1 hour prior to infusion
		Antihistamine	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or IV antihistamine	At least 30 minutes prior to infusion
		Antipyretic	Oral acetaminophen (500 mg to 1000 mg)	At least 30 minutes prior to infusion
Cycles 3+	Patients who experienced any grade CRS with the previous dose	Corticosteroid	Dexamethasone 20 mg (preferred) IV or methylprednisolone 80 mg IV	Complete at least 1 hour prior to infusion
		Antihistamine	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or IV antihistamine	At least 30 minutes prior to infusion
		Antipyretic	Oral acetaminophen (500 mg to 1000 mg)	At least 30 minutes prior to infusion

Recommended premedications for LUNSUMIO VELO™[2]

The following premedications are recommended before LUNSUMIO VELO injection to reduce the risk of CRS

Premedication to be administered prior to LUNSUMIO VELO injection

Treatment cycle	Patients requiring premedication	Premedication	Dosage
Cycle 1	All patients	Corticosteroid	Dexamethasone 20 mg (preferred) oral or IV or methylprednisolone 80 mg oral or IV
		Antihistamine*	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or IV antihistamine
		Antipyretic*	Oral acetaminophen (500 mg to 1000 mg)
Cycles 2+	Patients who experienced any grade CRS with the previous dose	Corticosteroid	Dexamethasone 20 mg (preferred) oral or IV or methylprednisolone 80 mg oral or IV
		Antihistamine*	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or IV antihistamine
		Antipyretic*	Oral acetaminophen (500 mg to 1000 mg)

*Antihistamine and antipyretic premedications are optional in all cycles.

All premedications, including corticosteroids, can be given orally for LUNSUMIO VELO[2]

Important Safety Information (cont'd)

Infections

LUNSUMIO or LUNSUMIO VELO can cause serious or fatal infections.

Among patients who received LUNSUMIO at the recommended dosage in the clinical trial, serious infections, including opportunistic infections, occurred in 17%, with Grade 3 or 4 infections in 14% and fatal infections in 0.9% of patients. The most common Grade 3 or greater infections were pneumonia, sepsis, and upper respiratory infection.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO® [IV] can be administered after a dose delay[1]

Recommendations for restarting therapy after dose delay

Last dose administered	Time since last dose administered	Action for next dose(s)
LUNSUMIO [IV] 1 mg (Cycle 1 Day 1)	1 to 2 weeks	Administer 2 mg (Cycle 1 Day 8), then resume the planned treatment schedule.
	>2 weeks	Repeat 1 mg (Cycle 1 Day 1), then administer 2 mg (Cycle 1 Day 8) and resume the planned treatment schedule.
LUNSUMIO [IV] 2 mg (Cycle 1 Day 8)	1 to 2 weeks	Administer 60 mg (Cycle 1 Day 15), then resume the planned treatment schedule.
	>2 to <6 weeks	Repeat 2 mg (Cycle 1 Day 8), then administer 60 mg (Cycle 1 Day 15) and resume the planned treatment schedule.
	≥6 weeks	Repeat 1 mg (Cycle 1 Day 1) and 2 mg (Cycle 1 Day 8), then administer 60 mg (Cycle 1 Day 15) and resume the planned treatment schedule.
LUNSUMIO [IV] 60 mg (Cycle 1 Day 15)	1 to <6 weeks	Administer 60 mg (Cycle 2 Day 1), then resume the planned treatment schedule.
	≥6 weeks	Repeat 1 mg (Cycle 2 Day 1) and 2 mg (Cycle 2 Day 8), then administer 60 mg (Cycle 2 Day 15), followed by 30 mg (Cycle 3 Day 1) and then resume the planned treatment schedule.
LUNSUMIO [IV] 60 mg (Cycle 2 Day 1)	3 to <6 weeks	Administer 30 mg (Cycle 3 Day 1), then resume the planned treatment schedule.
	≥6 weeks	Repeat 1 mg (Cycle 3 Day 1) and 2 mg (Cycle 3 Day 8), then administer 30 mg (Cycle 3 Day 15),* followed by 30 mg (Cycle 4 Day 1) and then resume the planned treatment schedule.
LUNSUMIO [IV] 30 mg (Cycle 3 onwards)	3 to <6 weeks	Administer 30 mg, then resume the planned treatment schedule.
	≥6 weeks	Repeat 1 mg on Day 1 and 2 mg on Day 8 during the next cycle, then administer 30 mg on Day 15,* followed by 30 mg on Day 1 of subsequent cycles.

*For the Day 1, Day 8, and Day 15 doses in the next cycle, administer premedication as per the table on page 16 for all patients.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Restarting LUNSUMIO VELO™ after dose delay[2]

Recommendations for restarting therapy after dose delay

Last dose administered	Time since last dose administered	Action for next dose(s)
LUNSUMIO VELO 5 mg (Cycle 1 Day 1)	1 to 2 weeks	Administer 45 mg (Cycle 1 Day 8),† then resume the planned treatment schedule.
	>2 weeks	Repeat 5 mg (Cycle 1 Day 1),† then administer 45 mg (Cycle 1 Day 8)† and resume the planned treatment schedule.
LUNSUMIO VELO 45 mg (Cycle 1 Day 8)	1 to <6 weeks	Administer 45 mg (Cycle 1 Day 15),† then resume the planned treatment schedule.
	≥6 weeks	Repeat 5 mg,† then administer 45 mg (Cycle 1 Day 15)† 7 days later and resume the planned treatment schedule.
LUNSUMIO VELO 45 mg (Cycle 1 Day 15)	1 to <6 weeks	Administer 45 mg (Cycle 2 Day 1), then resume the planned treatment schedule.
	≥6 weeks	Repeat 5 mg (Cycle 2 Day 1),† then administer 45 mg (Cycle 2 Day 8)† followed by 45 mg on Day 1 of subsequent cycles.
LUNSUMIO VELO 45 mg (Cycle 2 onwards)	3 to <6 weeks	Administer 45 mg, then resume the planned treatment schedule.
	≥6 weeks	Repeat 5 mg† on Day 1 during the next cycle, then administer 45 mg† on Day 8, followed by 45 mg on Day 1 of subsequent cycles.

†Administer premedication as per Cycle 1.

Important Safety Information (cont'd)

Infections (cont'd)

Among patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial, serious infections, including opportunistic infections, occurred in 17%, with Grade 3 or 4 infections in 16%, and fatal infections in 3.2% of patients. The most common Grade 3 or greater infections were pneumonia, sepsis, and COVID-19.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection **5 mg | 45 mg**

Preparation, administration, and storage of LUNSUMIO®[1]

Preparing LUNSUMIO

- **To prevent medication errors, check the vial labels to ensure that the drug being prepared and administered is LUNSUMIO for intravenous infusion. A peel-off label is provided on the LUNSUMIO Prescribing Information that should be attached to the final prepared solution. Remove the peel-off label from the Prescribing Information in the LUNSUMIO carton before discarding the carton. Affix the peel-off label to the diluted LUNSUMIO infusion bag**

Use aseptic technique to prepare LUNSUMIO

- Inspect the vial visually for any particulate matter, prior to administration. Do not use if the solution is discolored or cloudy, or if foreign particles are present
- Determine the dose, the total volume of LUNSUMIO solution required, and the number of LUNSUMIO vials needed

Diluting LUNSUMIO

1. Withdraw the volume from an infusion bag of 0.9% Sodium Chloride Injection, USP or 0.45% Sodium Chloride Injection, USP equal to the volume of the LUNSUMIO required for the patient's dose and discard. Only use infusion bags made of polyvinyl chloride (PVC) or polyolefins (PO) such as polyethylene (PE) and polypropylene (PP)
2. Withdraw the required volume of LUNSUMIO from the vial using a sterile needle and syringe and dilute into the infusion bag of 0.9% Sodium Chloride Injection, USP or 0.45% Sodium Chloride Injection, USP **according to the table below**. Discard any unused portion left in the vial

Dilution of LUNSUMIO

Dose of LUNSUMIO	Volume of LUNSUMIO	Size of 0.9% or 0.45% Sodium Chloride injection infusion bag
1 mg	1 mL	50 mL 100 mL
2 mg	2 mL	50 mL 100 mL
60 mg	60 mL	100 mL 250 mL
30 mg	30 mL	50 mL 100 mL 250 mL

3. Gently mix the IV bag by slowly inverting the bag. **Do not shake**
4. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if visibly opaque particles, discoloration, or foreign particles are observed

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO™ full Prescribing Information.

IV INFUSION

Diluting LUNSUMIO (cont'd)

5. Apply the peel-off label from the Prescribing Information to the infusion bag
6. Immediately use diluted LUNSUMIO infusion solution. If not used immediately, the diluted solution can be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours and at ambient temperature of 9°C to 30°C (48°F to 86°F) for up to 16 hours. Prior to administration, ensure the infusion solution comes to reach room temperature

Administering, storing, and handling LUNSUMIO

Administration of LUNSUMIO

- Administer LUNSUMIO as an IV infusion only
- **Do not use an in-line filter to administer LUNSUMIO**
- Do not mix LUNSUMIO with, or administer through the same infusion line as, other medicinal products
- No incompatibilities have been observed with infusion sets or infusion aids with product contacting materials of PVC, PE, polyurethane (PUR), polybutadiene (PBD), silicone, acrylonitrile butadiene styrene (ABS), polycarbonate (PC), polyetherurethane (PEU), fluorinated ethylene propylene (FEP), or polytetrafluorethylene (PTFE), or with drip chamber filter membrane composed of polyamide (PA)

How LUNSUMIO is supplied, stored, and handled

LUNSUMIO is a sterile, colorless, preservative-free solution for IV infusion supplied as follows:

- One 1 mg/mL single-dose vial in a carton (NDC 50242-159-01)
- One 30 mg/30 mL (1 mg/mL) single-dose vial in a carton (NDC 50242-142-01)
- Store refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. **Do not freeze. Do not shake**

Important Safety Information (cont'd)

Infections (cont'd)

Monitor patients for signs and symptoms of infection prior to and during treatment with LUNSUMIO or LUNSUMIO VELO and treat appropriately. LUNSUMIO or LUNSUMIO VELO should not be administered in the presence of active infection. Caution should be exercised when considering the use of LUNSUMIO or LUNSUMIO VELO in patients with a history of recurring or chronic infections (eg, chronic, active Epstein-Barr Virus), with underlying conditions that may predispose to infections, or who have had significant prior immunosuppressive treatment. Administer prophylactic antimicrobials according to guidelines. Withhold LUNSUMIO or LUNSUMIO VELO or consider permanent discontinuation of LUNSUMIO or LUNSUMIO VELO based on severity.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

Preparation, administration, and storage of LUNSUMIO VELO™[2]

Preparing LUNSUMIO VELO subcutaneous injection

- **To prevent medication errors, check the vial labels to ensure that the drug being prepared and administered is LUNSUMIO VELO for subcutaneous administration. A peel-off label is provided on the LUNSUMIO VELO Prescribing Information that should be attached to the final prepared syringe. Remove the peel-off label from the Prescribing Information in the LUNSUMIO VELO carton before discarding the carton. Affix the peel-off label to the prepared LUNSUMIO VELO syringe**
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the solution is discolored or cloudy, or if foreign particles are present
- Each LUNSUMIO VELO 5 mg/0.5 mL or 45 mg/mL vial is supplied as a ready-to-use solution that does not need dilution prior to subcutaneous administration. LUNSUMIO VELO vials are for one-time use in one patient only
- No incompatibilities between LUNSUMIO VELO and PP or PC syringe material, stainless-steel transfer and injection needles, and PE or PP syringe closing caps have been observed

Preparation of the syringe

1. Use aseptic technique to prepare LUNSUMIO VELO

2. Select the appropriate strength vial based on the prescribed dose

3. Withdraw the required volume of LUNSUMIO VELO solution from the vial with a syringe and an appropriately sized transfer needle (18 gauge to 21 gauge recommended). The smallest syringe that can accurately deliver the injection volume should be used. Discard any unused portion left in the vial

4. Remove the transfer needle and attach an appropriately sized injection needle (25 gauge to 30 gauge recommended)

5. Apply peel-off label from the Prescribing Information to the prepared drug product

6. Once transferred from the vial to the syringe, LUNSUMIO VELO solution for injection should be injected immediately because LUNSUMIO VELO solution for injection does not contain any antimicrobial preservatives

Storage of the prepared syringe

- The prepared syringe should be used immediately. If not used immediately, replace the transfer needle with a syringe closing cap. **Do not attach an injection needle**
- The capped syringe can be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 32 hours protected from light and/or at 9°C to 25°C (37°F to 77°F) for up to 8 hours at ambient light
- Once removed from refrigerated storage, the solution can be equilibrated to ambient temperature up to 25°C (77°F) prior to administration to support patient comfort. Do not warm LUNSUMIO VELO in any other way

Important Safety Information (cont'd)

Hemophagocytic Lymphohistiocytosis (HLH)

LUNSUMIO or LUNSUMIO VELO can cause fatal or serious HLH. HLH is a potentially life-threatening, hyperinflammatory syndrome that is independent of CRS. Common manifestations include fever, elevated ferritin, hemophagocytosis, cytopenias, coagulopathy, hepatitis, and splenomegaly.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO® and LUNSUMIO VELO full Prescribing Information.

SUBQ INJECTION

Administering, storing, and handling of LUNSUMIO VELO

Administration of LUNSUMIO VELO subcutaneous injection

- Inject the required volume of LUNSUMIO VELO into the subcutaneous tissue of the abdomen or thigh, changing the site of injection with each dose
- Do not inject into tattoos, moles, or scars, or areas where the skin is red, bruised, tender, hard, or not intact
- The dose should be administered subcutaneously over approximately 30 seconds to 1 minute

How LUNSUMIO VELO is supplied, stored, and handled

- LUNSUMIO VELO is a sterile, colorless to slightly brownish-yellow, preservative-free solution for subcutaneous injection supplied as follows:
  - One 5 mg/0.5 mL single-dose vial in a carton (NDC 50242-177-01)
  - One 45 mg/mL single-dose vial in a carton (NDC 50242-201-01)
- Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. **Do not freeze. Do not shake**

The prepared syringe can be capped and stored for later use. See page 22 for details

Important Safety Information (cont'd)

Hemophagocytic Lymphohistiocytosis (HLH) (cont'd)

Across a broader clinical trial population, HLH occurred in 0.5% (7/1536) of patients. Most cases (5/7) were identified within the first 28 days following initiation of LUNSUMIO or LUNSUMIO VELO, with 3 cases preceded by diagnosed or suspected CRS. Of the 7 cases of HLH, 6 had fatal outcomes, with 2 deaths from HLH alone and 4 deaths with concurrent unresolved HLH. Of the 7 cases of HLH, 4 occurred in the context of concurrent EBV and/or CMV infection.

Monitor for clinical signs and symptoms of HLH. Consider HLH when the presentation of CRS is atypical or prolonged, or when there are features of macrophage activation. For suspected HLH, interrupt LUNSUMIO or LUNSUMIO VELO and treat promptly for HLH per current practice guidelines.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO® [IV] safety profile[1]

Adverse reactions (≥10%) in patients with relapsed or refractory FL who received LUNSUMIO [IV] (n=90)

Adverse reactions*	All Grades (%)	Grade 3 or 4 (%)
Cytokine release syndrome	44	2.2
Fatigue†	42	0
Pyrexia	29	1.1‡
Edema†	17	1.1
Chills	13	1.1‡
Rash†	39	4.4‡
Pruritus	21	0
Dry skin	16	0
Skin exfoliation	10	0
Headache†	32	1.1‡
Peripheral neuropathy†	20	0
Dizziness†	12	0
Musculoskeletal pain†	28	1.1‡
Arthralgia	11	0
Cough†	22	0
Dyspnea†	11	1.1‡
Diarrhea	17	0
Nausea	17	0
Abdominal pain†	12	1.1‡
Upper respiratory tract infection†	14	2.2‡
Urinary tract infection†	10	1.1‡
Insomnia	12	0

*Adverse reactions were graded based on CTCAE Version 4.0, with the exception of CRS, which was graded per ASTCT 2019 criteria.
†Includes grouped terms as defined by the FDA. Definitions can be found in the LUNSUMIO [IV] Prescribing Information.
‡Only Grade 3 adverse reactions occurred.

LUNSUMIO VELO™ safety profile[2]

Adverse reactions (≥10%) in patients with relapsed or refractory FL who received LUNSUMIO VELO (n=94)

Adverse reactions§	All Grades (%)	Grade 3 or 4 (%)
Cytokine release syndrome	30	2.1
Injection site reactions‖	69	0
Fatigue¶	39	0
Edema¶	13	0
Pyrexia	11	1.1
Chills	11	0
Rash¶	35	3.2
Dry skin	11	0
Headache	17	0
Peripheral neuropathy¶	11	0
Dizziness¶	10	0
Musculoskeletal pain¶	20	0
Arthralgia	13	0
Cough	13	0
Dyspnea	11	0
Diarrhea	20	0
Nausea	14	0
Constipation	14	0
Abdominal pain	13	0
COVID-19#**	27	4.3
Upper respiratory tract infection¶	15	2.1
Pneumonia¶	13	4.3
Insomnia	15	0

Fatal adverse reactions occurred in 4.3% of patients from COVID-19 (3.2%) and HLH (1.1%).[2]

§Adverse reactions were graded based on CTCAE Version 4.0, with the exception of CRS, which was graded per ASTCT 2019 criteria.
‖Injection site reactions includes injection site reaction, injection site discharge, injection site erythema, injection site edema, injection site pain, injection site pruritus, and injection site rash.
¶Includes grouped terms as defined by the FDA. Definitions can be found in the LUNSUMIO VELO Prescribing Information.
#Adverse reaction with fatal outcome.
**Grade 5 COVID-19 occurred in 3.2% of patients.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO® [IV] laboratory abnormalities[1]

Select laboratory abnormalities (≥20%) that worsened from baseline in patients with relapsed or refractory FL who received LUNSUMIO [IV] (n=90)*

Laboratory abnormality	All Grades (%)	Grade 3 or 4 (%)
Lymphocyte count decreased	100	98
Hemoglobin decreased	68	12
Neutrophils decreased	58	40
Platelets decreased	46	10
Phosphate decreased	78	46
Glucose increased	42	42
Aspartate aminotransferase increased	39	4.4
Gamma-glutamyl transferase increased	34	9
Magnesium decreased	34	0
Potassium decreased	33	6
Alanine aminotransferase increased	32	7
Uric acid increased	22	22

*The denominator used to calculate the rate varied from 72 to 90 based on the number of patients with a baseline value and at least one post-treatment value.

LUNSUMIO VELO™ laboratory abnormalities[2]

Select laboratory abnormalities (≥20%) that worsened from baseline in patients with relapsed or refractory FL who received LUNSUMIO VELO (n=94)†

Laboratory abnormality	All Grades (%)	Grade 3 or 4 (%)
Lymphocyte count decreased	84	69
Hemoglobin decreased	60	10
Neutrophils decreased	50	26
Platelets decreased	33	6.4
Phosphate decreased	48	11
Alanine aminotransferase increased	34	1.1
Gamma-glutamyl transferase increased	31	1.1
Uric acid increased	28	28
Aspartate aminotransferase increased	28	2.1
Potassium decreased	27	0
Magnesium decreased	25	2.1

†The denominator used to calculate the rate varied from 85 to 94 based on the number of patients with a baseline value and at least one post-treatment value.

Important Safety Information (cont'd)

Cytopenias

LUNSUMIO or LUNSUMIO VELO can cause serious or severe cytopenias, including lymphopenia, neutropenia, anemia, and thrombocytopenia.

Among patients who received LUNSUMIO at the recommended dosage in the clinical trial, Grade 3 or 4 decreased lymphocytes occurred in 92%, decreased neutrophils in 38%, decreased hemoglobin in 19%, and decreased platelets in 12% of patients. Grade 4 decreased lymphocytes occurred in 71%, decreased neutrophils in 19%, and decreased platelets in 5% of patients. Febrile neutropenia occurred in 2% of patients.

Among patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial, Grade 3 or 4 decreased lymphocytes occurred in 69%, decreased neutrophils occurred in 26%, decreased hemoglobin in 10%, and decreased platelets in 10% of patients. Grade 4 decreased neutrophils occurred in 13% and decreased platelets in 6% of patients. Grade 4 decreased lymphocytes occurred in 22%, decreased neutrophils in 9%, and decreased platelets in 3.2% of patients. Febrile neutropenia occurred in 2.1% of patients.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Important Safety Information (cont'd)

Cytopenias (cont'd)

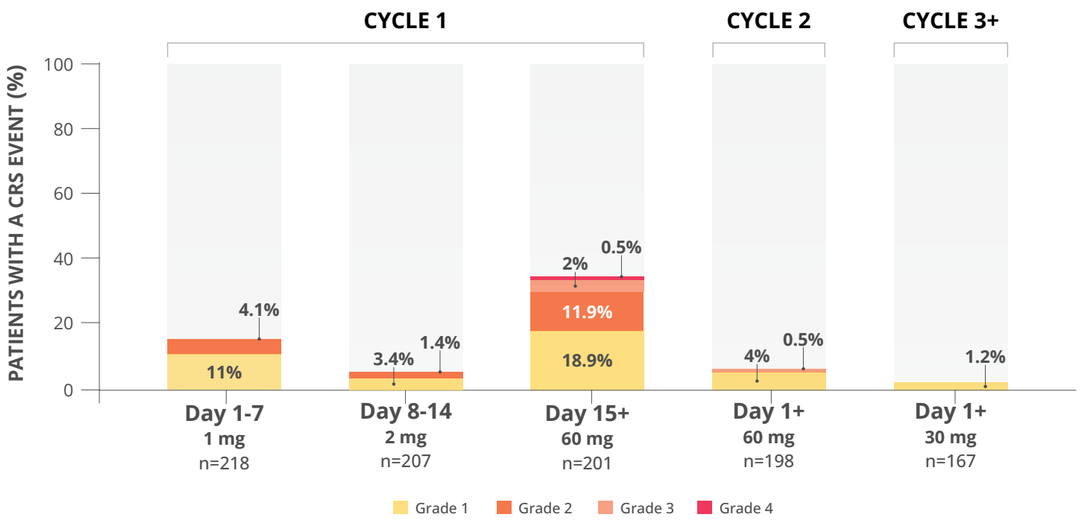
Monitor complete blood counts throughout treatment. Based on the severity of cytopenias, temporarily withhold or permanently discontinue LUNSUMIO or LUNSUMIO VELO. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection **5 mg | 45 mg**

CRS events with LUNSUMIO® [IV] were generally manageable[1,7,11]*

Patients with CRS events by grade and cycle in the pooled LUNSUMIO [IV] safety population[1,11]



- CRS of any grade occurred in 39% (86/218) of patients[1,11]
- Among patients who experienced a CRS event, 93% (80/86) were Grade 1-2[11]
- CRS events with LUNSUMIO [IV] occurred predominantly in Cycle 1 and were mainly associated with Day 1 and Day 15 dose administrations[1,11]
- Most cases of CRS occurred following doses of 1 mg on Cycle 1 Day 1 (15%), 2 mg on Cycle 1 Day 8 (5%), and 60 mg on Cycle 1 Day 15 (33%). Five percent of patients experienced CRS after receiving 60 mg on Cycle 2 Day 1 with 1% of patients experiencing CRS following subsequent dosages of LUNSUMIO [IV][1]
- <1% of patients discontinued treatment with LUNSUMIO [IV] due to CRS[11]

Median time to CRS onset from the start of infusion with LUNSUMIO [IV][1]

Cycle 1	Day 1	5 hours (range: 1 to 72 hours)
	Day 8	28 hours (range: 5 to 72 hours)
	Day 15	25 hours (range: 0.1 to 384 hours)
Cycle 2	Day 1	46 hours (range: 12 to 72 hours)

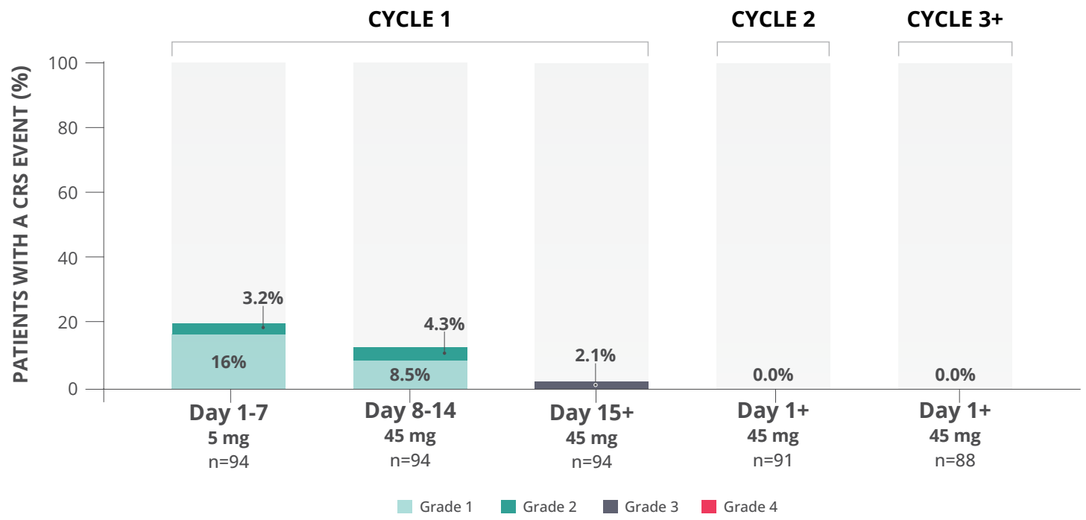
All CRS events were effectively mitigated with supportive treatment[7]*

*Please refer to the full Prescribing Information (Section 2.4) for CRS Grading and Management.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

LUNSUMIO VELO™: CRS events were primarily low grade and mostly occurred after the first 2 doses[2,10,11†]

Patients with CRS events by grade and cycle in the LUNSUMIO VELO safety population[2,11]



- CRS of any grade occurred in 30% (28/94) of patients[2]
- CRS occurred most commonly after the first two doses: 19% of patients experienced CRS after the Cycle 1 Day 1 dose, 13% after the Cycle 1 Day 8 dose, and 2.1% after the Cycle 1 Day 15 dose[2†]
- CRS resolved in all patients, after a median duration of 2 days (range: 1 to 15 days)[2]

Median time to CRS onset from the start of injection with LUNSUMIO VELO[2,11]

Cycle 1	Day 1	17 hours (range: 7 to 33 hours)
	Day 8	62 hours (range: 30 to 113 hours)
	Day 15	36 hours (range: 23 to 48 hours)

Plasma concentrations of cytokines (IL-2, IL-6, IL-10, TNF-α, and IFN-γ) were measured in patients administered LUNSUMIO VELO.[2]

- Transient elevations were observed at doses ≥1.6 mg
- After administration of the recommended dosage of LUNSUMIO VELO, the highest elevation of cytokines was generally observed within 48 hours after the first dose on Cycle 1 Day 8
  - Levels generally returned to baseline prior to the third full dose on Cycle 2 Day 1
- **The observed pattern of cytokine release appeared slower and reduced relative to LUNSUMIO [IV]**

†Please refer to the full Prescribing Information (Section 2.4) for CRS Grading and Management.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

Monitoring for signs and symptoms of CRS

Depending on the severity of CRS, signs and symptoms exist on a broad spectrum from mild to life threatening. These symptoms, which can be progressive, must include pyrexia at the onset and may include hypotension, hypoxia, and end-organ dysfunction.[12]

Most common CRS signs and symptoms with LUNSUMIO® [IV] and LUNSUMIO VELO™[11]

Symptoms	LUNSUMIO [IV] (%) (86/218)	LUNSUMIO VELO (%) (28/94)
Fever	98%	96%
Chills	36%	11%
Hypotension	35%	21%
Tachycardia	24%	14%
Hypoxia	22%	21%
Headache	16%	11%

Important Safety Information (cont'd)

Tumor Flare

LUNSUMIO or LUNSUMIO VELO can cause serious or severe tumor flare.

Among patients who received LUNSUMIO at the recommended dosage in the clinical trial, tumor flare occurred in 4%. Among patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial, tumor flare occurred in 1.1% of patients. Manifestations included new or worsening pleural effusions, localized pain and swelling at the sites of lymphoma lesions, and tumor inflammation.

Patients with bulky tumors or disease located in close proximity to airways or a vital organ should be monitored closely during initial therapy. Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare. If compression or obstruction develops, institute standard treatment of these complications.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

IV INFUSION SUBQ INJECTION

Patient CRS resource

A resource to provide information on the signs and symptoms of CRS and when to seek immediate medical attention

The Patient Wallet Card is a resource that patients should carry throughout the course of treatment with LUNSUMIO or LUNSUMIO VELO. It provides:

- A list of signs and symptoms of CRS
- When to seek emergency help right away
- Details about their treatment
- Information for the treating doctor on CRS
- A QR code to a CRS grading tool and recommended management based on grade of CRS experienced

Scan code to download the Patient Wallet Card

Important Safety Information (cont'd)

Risk of Medication Errors with Incorrect Product Use

Mosunetuzumab-axgb is available in two formulations: as an injection for intravenous use (LUNSUMIO) and as an injection for subcutaneous use (LUNSUMIO VELO). Check the product labels to ensure that the correct formulation is being prescribed, dispensed, and administered to the patient. Do not substitute LUNSUMIO for or with LUNSUMIO VELO.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO® dosage modifications for CRS[1]

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, withhold LUNSUMIO infusion until CRS resolves, and manage according to the recommendations in this table and per current practice guidelines. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS.

Recommendations for management of CRS with LUNSUMIO

Grade*	Presenting symptoms	Actions†
Grade 1	Fever ≥100.4°F (38°C)‡	• Withhold current infusion of LUNSUMIO and manage per current practice guidelines – If symptoms resolve, restart infusion at the same rate • Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO§ • Administer premedication‖ prior to next dose of LUNSUMIO and monitor patient more frequently
Grade 2	Fever ≥100.4°F (38°C)‡ with: Hypotension not requiring vasopressors and/or Hypoxia requiring low-flow oxygen¶ by nasal cannula or blow-by	• Withhold current infusion of LUNSUMIO and manage per current practice guidelines – If symptoms resolve, restart infusion at 50% rate • Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO§ • Administer premedication‖ prior to next dose of LUNSUMIO and consider infusing the next dose at 50% rate • For the next dose of LUNSUMIO, monitor more frequently and consider hospitalization
		Recurrent Grade 2 CRS • Manage per Grade 3 CRS

*Based on ASTCT 2019 grading for CRS.
†If CRS is refractory to management, consider other causes including hemophagocytic lymphohistiocytosis.
‡Premedication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.
§Refer to page 18 for information on restarting LUNSUMIO after dose delays.
‖Refer to page 16 for additional information on premedication.
¶Low-flow oxygen defined as oxygen delivered at <6 L/minute; high-flow oxygen defined as oxygen delivered at ≥6 L/minute.

Important Safety Information (cont'd)

Embryo-Fetal Toxicity

Based on its mechanism of action, LUNSUMIO or LUNSUMIO VELO may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating LUNSUMIO or LUNSUMIO VELO. Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO or LUNSUMIO VELO and for 3 months after the last dose.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO™ full Prescribing Information.

LUNSUMIO dosage modifications for CRS[1] (cont'd)

Recommendations for management of CRS with LUNSUMIO (cont'd)

Grade#	Presenting symptoms	Actions**
Grade 3	Fever ≥100.4°F (38°C)†† with: Hypotension requiring a vasopressor (with or without vasopressin) and/or Hypoxia requiring high-flow oxygen‖‖ by nasal cannula, face mask, non-rebreather mask, or Venturi mask	• Withhold LUNSUMIO, manage per current practice guidelines, and provide supportive therapy, which may include intensive care • Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO‡‡ • Administer premedication§§ prior to next dose of LUNSUMIO and infuse the next dose at 50% rate • Hospitalize for the next dose of LUNSUMIO
		Recurrent Grade 3 CRS • Permanently discontinue LUNSUMIO • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care
Grade 4	Fever ≥100.4°F (38°C)†† with: Hypotension requiring multiple vasopressors (excluding vasopressin) and/or Hypoxia requiring oxygen by positive pressure (eg, CPAP, BiPAP, intubation, and mechanical ventilation)	• Permanently discontinue LUNSUMIO • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care

#Based on ASTCT 2019 grading for CRS.
**If CRS is refractory to management, consider other causes including hemophagocytic lymphohistiocytosis.
††Premedication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.
‡‡Refer to page 18 for information on restarting LUNSUMIO after dose delays.
§§Refer to page 16 for additional information on premedication.
‖‖Low-flow oxygen defined as oxygen delivered at <6 L/minute; high-flow oxygen defined as oxygen delivered at ≥6 L/minute.

Important Safety Information (cont'd)

Most Common Adverse Reactions

The most common (≥20%) adverse reactions of LUNSUMIO are CRS (44%), fatigue (42%), rash (39%), headache (32%), pyrexia (29%), musculoskeletal pain (28%), cough (22%), pruritus (21%), and peripheral neuropathy (20%).

The most common (≥20%) adverse reactions of LUNSUMIO VELO are injection site reactions (69%), fatigue (39%), rash (35%), CRS (30%), COVID-19 infection (27%), musculoskeletal pain (20%), and diarrhea (20%).

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LUNSUMIO VELO™ dosage modifications for CRS[2]

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, withhold LUNSUMIO VELO until CRS resolves, and manage according to the recommendations in this table and per current practice guidelines. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS.

Recommendations for management of CRS with LUNSUMIO VELO

Grade*	Presenting symptoms	Actions†
Grade 1	Fever ≥100.4°F (38°C)‡	• Ensure CRS symptoms are resolved prior to the next dose of LUNSUMIO VELO§ • Administer premedication‖ prior to next dose of LUNSUMIO VELO and monitor patient more frequently
Grade 2	Fever ≥100.4°F (38°C)‡ with: Hypotension not requiring vasopressors and/or Hypoxia requiring low-flow oxygen¶ by nasal cannula or blow-by	• Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO VELO§ • Administer premedication‖ prior to next dose of LUNSUMIO VELO • For the next dose of LUNSUMIO VELO, monitor more frequently and consider hospitalization Recurrent Grade 2 CRS • Manage per Grade 3 CRS

*Based on ASTCT 2019 grading for CRS.
†If CRS is refractory to management, consider other causes including hemophagocytic lymphohistiocytosis.
‡Premedication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.
§Refer to page 19 for information on restarting LUNSUMIO VELO after dose delays.
‖Refer to page 17 for additional information on premedication.
¶Low-flow oxygen defined as oxygen delivered at <6 L/minute; high-flow oxygen defined as oxygen delivered at ≥6 L/minute.

Important Safety Information (cont'd)

Most Common Adverse Reactions (cont'd)

The most common Grade 3 to 4 laboratory abnormalities (≥10%) with LUNSUMIO are decreased lymphocyte count (92%), decreased phosphate (41%), increased glucose (40%), decreased neutrophil count (38%), decreased hemoglobin (19%), increased uric acid (15%), and decreased platelets (12%).

The most common Grade 3 to 4 laboratory abnormalities (≥15%) with LUNSUMIO VELO are decreased lymphocyte count (69%), decreased neutrophil count (26%), and increased uric acid (28%). Grade 4 laboratory abnormalities in >5% included lymphocyte count decreased (22%) and neutrophil count decreased (9%).

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO® and LUNSUMIO VELO full Prescribing Information.

SUBQ INJECTION

LUNSUMIO VELO dosage modifications for CRS[2] (cont'd)

Recommendations for management of CRS with LUNSUMIO VELO (cont'd)

Grade#	Presenting symptoms	Actions**
Grade 3	Fever ≥100.4°F (38°C)†† with: Hypotension requiring vasopressor (with or without vasopressin) and/or Hypoxia requiring high-flow oxygen‖‖ by nasal cannula, face mask, non-rebreather mask, or Venturi mask	• Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO VELO‡‡ • Administer premedication§§ prior to next dose of LUNSUMIO VELO • For the next dose of LUNSUMIO VELO, monitor more frequently and hospitalize for the next dose • If CRS occurred after 5 mg or 45 mg dose, administer 5 mg as the next dose. Resume treatment schedule after recovery. If the 5 mg dose is tolerated without Grade 3 CRS, resume subsequent doses at 45 mg Recurrent Grade 3 CRS • Permanently discontinue LUNSUMIO VELO • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care
Grade 4	Fever ≥100.4°F (38°C)†† with: Hypotension requiring multiple vasopressors (excluding vasopressin) and/or Hypoxia requiring oxygen by positive pressure (eg, CPAP, BiPAP, intubation, and mechanical ventilation)	• Permanently discontinue LUNSUMIO VELO • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care

#Based on ASTCT 2019 grading for CRS.
**If CRS is refractory to management, consider other causes including hemophagocytic lymphohistiocytosis.
††Premedication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.
‡‡Refer to page 19 for information on restarting LUNSUMIO VELO after dose delays.
§§Refer to page 17 for additional information on premedication.
‖‖Low-flow oxygen defined as oxygen delivered at <6 L/minute; high-flow oxygen defined as oxygen delivered at ≥6 L/minute.

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Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

Dosage modifications for neurologic toxicity, including ICANS, and other adverse reactions[1,2]

Recommendations for management of neurologic toxicity (including ICANS) for LUNSUMIO® [IV] or LUNSUMIO VELO™

Adverse reaction	Severity*†	Actions
Neurologic Toxicity* (including ICANS†)	Grade 1	• Continue LUNSUMIO [IV] or LUNSUMIO VELO and monitor neurologic toxicity symptoms • If ICANS, manage per current practice guidelines
	Grade 2	• Withhold LUNSUMIO [IV] or LUNSUMIO VELO until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 72 hours‡ • Provide supportive therapy, and consider neurologic evaluation • If ICANS, manage per current practice guidelines
	Grade 3	• Withhold LUNSUMIO [IV] or LUNSUMIO VELO until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 72 hours‡ • Provide supportive therapy, which may include intensive care, and consider neurology evaluation • If ICANS, manage per current practice guidelines • If recurrence of ICANS, permanently discontinue LUNSUMIO [IV] or LUNSUMIO VELO
	Grade 4	• Permanently discontinue LUNSUMIO [IV] or LUNSUMIO VELO • Provide supportive therapy, which may include intensive care, and consider neurology evaluation • If ICANS, manage per current practice guidelines

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
†Based on ASTCT 2019 grading for ICANS.
‡See page 18 for recommendations on restarting LUNSUMIO [IV] after dose delays. See page 19 for recommendations on restarting LUNSUMIO VELO after dose delays.

Important Safety Information (cont'd)

Drug Interactions

LUNSUMIO or LUNSUMIO VELO causes release of cytokines that may suppress activity of CYP450 enzymes, resulting in increased exposure of CYP450 substrates. Increased exposure of CYP450 substrates is more likely to occur after the first dose of LUNSUMIO or LUNSUMIO VELO on Cycle 1 Day 1 and up to 14 days after the 60 mg dose of LUNSUMIO on Cycle 2 Day 1 or the 45 mg dose of LUNSUMIO VELO on Cycle 1 Day 8 and during and after CRS. Monitor for toxicity or concentrations of drugs that are CYP450 substrates where minimal concentration changes may lead to serious adverse reactions. Consult the concomitant CYP450 substrate drug prescribing information for recommended dosage modification.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

IV INFUSION SUBQ INJECTION

Recommended dosage modifications for LUNSUMIO [IV] or LUNSUMIO VELO due to other adverse reactions[1,2]

For infections§

- **Grade 1-4:** Withhold LUNSUMIO [IV] or LUNSUMIO VELO in patients with active infection until the infection resolves‖
- **Grade 4:** Consider permanent discontinuation of LUNSUMIO [IV] or LUNSUMIO VELO

For neutropenia§

- **Absolute neutrophil count less than 0.5 x 10^9/L:** Withhold LUNSUMIO [IV] or LUNSUMIO VELO until absolute neutrophil count is 0.5 x 10^9/L or higher‖

For other adverse reactions§

- **Grade 3 or higher:** Withhold LUNSUMIO [IV] or LUNSUMIO VELO until the toxicity resolves to Grade 1 or baseline‖
- **Permanently discontinue** LUNSUMIO VELO if a Grade 4 injection site reaction occurs

§Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
‖See page 18 for recommendations on restarting LUNSUMIO [IV] after dose delays. See page 19 for recommendations on restarting LUNSUMIO VELO after dose delays.

Important Safety Information (cont'd)

Use in Specific Populations

Lactation

There is no information regarding the presence of mosunetuzumab-axgb in human milk, the effect on the breastfed child, or milk production. Because human IgG is present in human milk, and there is potential for mosunetuzumab-axgb absorption leading to B-cell depletion, advise women not to breastfeed during treatment with LUNSUMIO or LUNSUMIO VELO for 3 months after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

Genentech Patient Support Services are here to help patients and practices after LUNSUMIO® [IV] or LUNSUMIO VELO™ has been prescribed

Support for patients

Financial assistance is available to help eligible patients who have been prescribed LUNSUMIO [IV] or LUNSUMIO VELO, regardless of their situation

- ✓ If eligible commercially insured patients need assistance with their out-of-pocket costs, the Genentech Oncology Co-pay Assistance Program may help*
- ✓ If eligible publicly- or commercially-insured patients have difficulty paying for their co-pay, co-insurance, or other out-of-pocket costs, Genentech Access Solutions can refer them to an independent co-pay assistance foundation supporting their diagnosis†
- ✓ If patients don't have health insurance coverage or have financial concerns and meet eligibility criteria, they may be able to get free medicine from the Genentech Patient Foundation‡

For more information, contact your local Genentech representative, visit LUNSUMIO-hcp.com, or call (888) 249-4918

*Eligibility criteria and benefit limits apply. Not valid for patients whose prescriptions are reimbursed under any federal or state government programs to pay for their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.

†Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech does not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

‡To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Support for practices

Genentech Access Solutions provides helpful access and reimbursement support after LUNSUMIO [IV] or LUNSUMIO VELO has been prescribed. We can help your patients and practice by providing§:

- ✓ Benefits investigations (BIs)
- ✓ Assistance in identifying the appropriate financial support and other resources for their situation
- ✓ Prior authorization (PA) resources
- ✓ Resources for denials and appeals
- ✓ Sample coding information
- ✓ Information about authorized specialty pharmacies (SPs) and specialty distributors

§The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

3L+=third-line or later; AE=adverse event; ASTCT=American Society for Transplantation and Cellular Therapy; $AUC_{0\text{-}84}$=cumulative area under the concentration-time curve over 0-84 days; auto-SCT=autologous stem cell transplant; BiPAP=bilevel positive airway pressure; CAR-T=chimeric antigen receptor-T cell; CD=cluster of differentiation; CI=confidence interval; CPAP=continuous positive airway pressure; CR=complete response; CRS=cytokine release syndrome; CTCAE=Common Terminology Criteria for Adverse Events; $C_{trough(C3)}$=observed Cycle 3 serum trough concentration; DOCR=duration of complete response; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; EZH2=enhancer of zeste homolog 2; FDA=Food and Drug Administration; FL=follicular lymphoma; FLIPI=Follicular Lymphoma International Prognostic Index; GMR=geometric mean ratio; HLH=hemophagocytic lymphohistiocytosis; ICANS=immune effector cell-associated neurotoxicity syndrome; IFN-γ=interferon-gamma; IL-2=interleukin-2; IL-6=interleukin-6; IL-10=interleukin-10; IRF=independent review facility; IV=intravenous; mDOCR=median duration of complete response; mDOR=median duration of response; MOA=mechanism of action; NCCN=National Comprehensive Cancer Network® (NCCN®); NCI=National Cancer Institute; NDC=National Drug Code; NE=not estimable; NR=not reached; ORR=overall response rate; PI3K=phosphoinositide 3-kinase; PK=pharmacokinetics; PKNI=pharmacokinetic non-inferiority; POD24=progression of disease within 24 months from the start of initial therapy; PR=partial response; PTS=patients; SD=stable disease; SUBQ=subcutaneous; TNF-α=tumor necrosis factor-alpha; USP=United States Pharmacopeia.

References: 1. LUNSUMIO. Prescribing Information. Genentech, Inc. **2.** LUNSUMIO VELO. Prescribing Information. Genentech, Inc. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-cell Lymphomas V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 18, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org **4.** Rivas-Delgado A, Magnano L, Moreno-Velázquez M, et al. Response duration and survival shorten after each relapse in patients with follicular lymphoma treated in the rituximab era. *Br J Haematol*. 2019;184(5):753-759. doi:10.1111/bjh.15708. **5.** Sun LL, Ellerman D, Mathieu M, et al. Anti-CD20/CD3 T cell-dependent bispecific antibody for the treatment of B cell malignancies. *Sci Transl Med*. 2015;7(287):287ra70. doi:10.1126/scitranslmed.aaa4802. **6.** Ferl GZ, Reyes A, Sun LL, et al. A preclinical population pharmacokinetic model for anti-CD20/CD3 T-cell-dependent bispecific antibodies. *Clin Transl Sci*. 2018;11(3):296-304. doi:10.1111/cts.12535. **7.** Budde LE, Sehn LH, Matasar M, et al. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. *Lancet Oncol*. 2022;23(8):1055-1065. doi:10.1016/S1470-2045(22)00335-7. **8.** BLA Multi-disciplinary Review and Evaluation {BLA 761263, Lunsumio (Mosunetuzumab)}. US Food and Drug Administration. January 2020. Accessed September 14, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761263Orig1s000MultidisciplineR.pdf. **9.** Shadman M, Bartlett NL, Matasar M, et al. Mosunetuzumab continues to demonstrate clinically meaningful outcomes in patients with relapsed and/or refractory follicular lymphoma after ≥2 prior therapies including those with a history of POD24: 4-year follow-up of a pivotal Phase II study. Presented at: The 66th American Society of Hematology Annual Meeting. December 7-10, 2024. P4407. **10.** Bartlett NL, Sehn LH, Assouline S, et al. Presented at: The 66th American Society of Hematology Annual Meeting. December 7-10, 2024. P1645. **11.** Data on file. Genentech, Inc. **12.** Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. *Biol Blood Marrow Transplant*. 2019;25(4):625-638. doi:10.1016/j.bbmt.2018.12.758.

Lunsumio® mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™ mosunetuzumab-axgb subcutaneous injection 5 mg | 45 mg

LIGHTING THE WAY FOR PATIENTS WITH 3L+ FL

Impressive patient responses from a first-in-class T-cell engaging bispecific antibody[1]

80% (n=72/90) of patients treated with LUNSUMIO® [IV] achieved an overall response (95% CI: 70%-88%)

Durable remission from a fixed-duration therapy[1]

23-month mDOR (95% CI: 10 months-NR)*; the median follow-up for DOR was 14.9 months for LUNSUMIO [IV]

LUNSUMIO VELO™ is available as a subcutaneous injection administered in ~1 minute[2†]

Scan to visit LUNSUMIO-hcp.com to learn more

*Kaplan-Meier estimate.[1]
†Refers to the injection time and does not include other aspects of treatment; actual clinical time may vary.[2]

Indication

LUNSUMIO (mosunetuzumab-axgb) or LUNSUMIO VELO is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

BOXED WARNING

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO or LUNSUMIO VELO. Initiate treatment with the LUNSUMIO or LUNSUMIO VELO step-up dosing schedule to reduce the risk of CRS. Withhold LUNSUMIO or LUNSUMIO VELO until CRS resolves or permanently discontinue based on severity.

Please see Important Safety Information, including **BOXED WARNING**, throughout this brochure as well as the accompanying LUNSUMIO and LUNSUMIO VELO full Prescribing Information.

Lunsumio®
mosunetuzumab-axgb
injection for intravenous use 1 mg | 30 mg

Lunsumio VELO™
mosunetuzumab-axgb
subcutaneous injection **5 mg | 45 mg**

Genentech
A Member of the Roche Group

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LUNSUMIO safely and effectively. See full prescribing information for LUNSUMIO.

LUNSUMIO® (mosunetuzumab-axgb) injection, for intravenous use
Initial U.S. Approval: 2022

WARNING: CYTOKINE RELEASE SYNDROME
See full prescribing information for complete boxed warning.

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO. Initiate treatment with the LUNSUMIO step-up dosing schedule to reduce the risk of CRS. Withhold LUNSUMIO until CRS resolves or permanently discontinue based on severity. (2.1, 2.4, 5.1)

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.1, 2.3, 2.5)	12/2025
Warnings and Precautions (5.1, 5.5, 5.7)	12/2025

----------INDICATIONS AND USAGE----------

LUNSUMIO is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). (1.1)

----------DOSAGE AND ADMINISTRATION----------

- **LUNSUMIO and LUNSUMIO VELO have different dosage and administration instructions. Administer LUNSUMIO only as an intravenous infusion. (2.1)**
- Premedicate to reduce risk of CRS and infusion-related reactions. (2.3, 5.1)
- Recommended dosage for LUNSUMIO for intravenous infusion (2.2):

Day of Treatment [a]		Intravenous Dose of LUNSUMIO	Rate of Infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4 hours.
	Day 8	2 mg	
	Day 15	60 mg	
Cycle 2	Day 1	60 mg	Administer over 2 hours if infusions from Cycle 1 were well-tolerated.
Cycles 3+	Day 1	30 mg	

[a] Cycle length = 21 days

- See Full Prescribing Information for instructions on preparation and administration. (2.5)

----------DOSAGE FORMS AND STRENGTHS----------

Injection:

- 1 mg/mL solution in a single-dose vial. (3)
- 30 mg/30 mL (1 mg/mL) solution in a single-dose vial. (3)

----------CONTRAINDICATIONS----------

None. (4)

----------WARNINGS AND PRECAUTIONS----------

- Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome: Can cause serious and life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). Monitor patients for signs and symptoms of neurologic toxicity during treatment; withhold or permanently discontinue based on severity. (5.2)
- Infections: Can cause serious or fatal infections. Monitor patients for signs and symptoms of infection, including opportunistic infections, and treat as needed. (5.3)
- Hemophagocytic Lymphohistiocytosis: Can cause serious or fatal reactions. For suspected cases, interrupt LUNSUMIO and evaluate and treat promptly. (5.4)
- Cytopenias: Monitor complete blood cell counts during treatment. (5.5)
- Tumor Flare: Can cause serious tumor flare reactions. Monitor patients at risk for complications of tumor flare. (5.6)
- Risk of Medication Errors with Incorrect Product Use: Ensure that the correct formulation is being prescribed, dispensed, and administered. (5.7)
- Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception. (5.8, 8.1, 8.3)

----------ADVERSE REACTIONS----------

The most common adverse reactions (≥ 20%) in patients with follicular lymphoma are CRS, fatigue, rash, headache, pyrexia, musculoskeletal pain, cough, pruritus, and peripheral neuropathy.

The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) are decreased lymphocyte count, decreased phosphate, increased glucose, decreased neutrophil count, increased uric acid, decreased hemoglobin, and decreased platelets. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 12/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO. Initiate treatment with the LUNSUMIO step-up dosing schedule to reduce the risk of CRS. Withhold LUNSUMIO until CRS resolves or permanently discontinue based on severity *[see Dosage and Administration (2.1 and 2.4) and Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

1.1 Follicular Lymphoma

LUNSUMIO is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate *[see Clinical Studies (14)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing Information

- **LUNSUMIO and LUNSUMIO VELO have different dosage and administration instructions *[see Dosage and Administration (2.2) and Warnings and Precautions (5.7)]*.**
    - **LUNSUMIO is for intravenous use only.**
    - **Check the product label to ensure that the correct formulation (LUNSUMIO or LUNSUMIO VELO) is being prescribed and administered.**
    - **Do not substitute LUNSUMIO for or with LUNSUMIO VELO.**
- Administer LUNSUMIO to well-hydrated patients.
- Premedicate before each dose in Cycle 1 and Cycle 2 *[see Dosage and Administration (2.3)]*.
- Administer only as an intravenous infusion through a dedicated infusion line. **Do not use an in-line filter to administer LUNSUMIO**. Drip chamber filters can be used to administer LUNSUMIO.
- LUNSUMIO should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity, including ICANS *[see Warnings and Precautions (5.1 and 5.2)]*.

2.2 Recommended Dosage

The recommended dosage for LUNSUMIO intravenous infusion is presented in Table 1.

Administer for 8 cycles, unless patients experience unacceptable toxicity or disease progression.

For patients who achieve a complete response, no further treatment beyond 8 cycles is required. For patients who achieve a partial response or have stable disease in response to treatment with LUNSUMIO after 8 cycles, an additional 9 cycles of treatment (17 cycles total) should be administered, unless a patient experiences unacceptable toxicity or disease progression.

Table 1. Recommended Dose and Schedule of LUNSUMIO Intravenous Infusion (21-Day Treatment Cycles)

Day of Treatment		Intravenous Dose of LUNSUMIO	Rate of Infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4 hours.
	Day 8	2 mg	
	Day 15	60 mg	
Cycle 2	Day 1	60 mg	Administer over 2 hours if infusions from Cycle 1 were well-tolerated.
Cycles 3+	Day 1	30 mg	

Table 2. Recommendations for Restarting Therapy with LUNSUMIO Intravenous Infusion After Dose Delay

Last Intravenous Dose Administered	Time Since Last Dose Administered	Action for Next Intravenous Dose(s)
1 mg Cycle 1 Day 1	1week to 2 weeks	Administer 2 mg (Cycle 1 Day 8), then resume the planned treatment schedule.
	Greater than 2 weeks	Repeat 1 mg (Cycle 1 Day 1), then administer 2 mg (Cycle 1 Day 8) and resume the planned treatment schedule.
2 mg Cycle 1 Day 8	1 week to 2 weeks	Administer 60 mg (Cycle 1 Day 15), then resume the planned treatment schedule.
	Greater than 2 weeks to less than 6 weeks	Repeat 2 mg (Cycle 1 Day 8), then administer 60 mg (Cycle 1 Day 15) and resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 1 mg (Cycle 1 Day 1) and 2 mg (Cycle 1 Day 8), then administer 60 mg (Cycle 1 Day 15) and resume the planned treatment schedule.
60 mg Cycle 1 Day 15	1 week to less than 6 weeks	Administer 60 mg (Cycle 2 Day 1), then resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 1 mg (Cycle 2 Day 1) and 2 mg (Cycle 2 Day 8), then administer 60 mg (Cycle 2 Day 15), followed by 30 mg (Cycle 3 Day 1) and then resume the planned treatment schedule.
60 mg Cycle 2 Day 1	3 weeks to less than 6 weeks	Administer 30 mg (Cycle 3 Day 1), then resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 1 mg (Cycle 3 Day 1) and 2 mg (Cycle 3 Day 8), then administer 30 mg (Cycle 3 Day 15)*, followed by 30 mg (Cycle 4 Day 1) and then resume the planned treatment schedule.
30 mg Cycle 3 onwards	3 weeks to less than 6 weeks	Administer 30 mg, then resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 1 mg on Day 1 and 2 mg on Day 8 during the next cycle, then administer 30 mg on Day 15*, followed by 30 mg on Day 1 of subsequent cycles.
* For the Day 1, Day 8, and Day 15 doses in the next cycle, administer premedication as per Table 3 for all patients.		

2.3 Recommended Premedication

Premedication to reduce the risk of CRS and infusion-related reactions are outlined in Table 3 *[see Warnings and Precautions (5.1)]*.

Table 3. Premedication to be Administered to Patients Prior to LUNSUMIO Intravenous Infusion

Treatment Cycle	Patients Requiring Premedication	Premedication	Dosage	Administration
Cycle 1 and Cycle 2	All patients	Corticosteroid	Dexamethasone 20 mg (preferred) intravenous or methylprednisolone 80 mg intravenous	Complete at least 1 hour prior to infusion
		Antihistamine	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or intravenous antihistamine	At least 30 minutes prior to infusion
		Antipyretic	Oral acetaminophen (500 mg to 1,000 mg)	At least 30 minutes prior to infusion
Cycles 3+	Patients who experienced any grade CRS with the previous dose	Corticosteroid	Dexamethasone 20 mg (preferred) intravenous or methylprednisolone 80 mg intravenous	Complete at least 1 hour prior to infusion
		Antihistamine	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or intravenous antihistamine	At least 30 minutes prior to infusion
		Antipyretic	Oral acetaminophen (500 mg to 1,000 mg)	At least 30 minutes prior to infusion

2.4 Dosage Modifications for Adverse Reactions

See Tables 4 and 5 for the recommended dosage modifications for adverse reactions of CRS and neurologic toxicity, including immune effector cell-associated neurotoxicity (ICANS). See Table 6 for the recommended dosage modifications for other adverse reactions following administration of LUNSUMIO.

Dosage Modifications for Cytokine Release Syndrome

Identify CRS based on clinical presentation *[see Warnings and Precautions (5.1)]*. Evaluate for and treat other causes of fever, hypoxia, and hypotension.

If CRS is suspected, withhold LUNSUMIO until CRS resolves, manage according to the recommendations in Table 4 and per current practice guidelines. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS.

Table 4. Recommendations for Management of Cytokine Release Syndrome with LUNSUMIO Intravenous Infusion

Grade[a]	Presenting Symptoms	Actions[b]
Grade 1	Fever ≥ 100.4°F (38°C)[c]	• Withhold current infusion of LUNSUMIO and manage per current practice guidelines. o If symptoms resolve, restart infusion at the same rate. • Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO.[d] • Administer premedication[e] prior to next dose of LUNSUMIO and monitor patient more frequently.

Grade[a]	Presenting Symptoms	Actions[b]
Grade 2	Fever ≥ 100.4°F (38°C)[c] with: Hypotension not requiring vasopressors and/or hypoxia requiring low-flow oxygen[f] by nasal cannula or blow-by.	• Withhold current infusion of LUNSUMIO and manage per current practice guidelines. ○ If symptoms resolve, restart infusion at 50% rate. • Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO.[d] • Administer premedication[e] prior to next dose of LUNSUMIO and consider infusing the next dose at 50% rate. • For the next dose of LUNSUMIO, monitor more frequently and consider hospitalization.
		Recurrent Grade 2 CRS • Manage per Grade 3 CRS.
Grade 3	Fever ≥ 100.4°F (38°C)[c] with: Hypotension requiring a vasopressor (with or without vasopressin) and/or hypoxia requiring high flow oxygen[f] by nasal cannula, face mask, non-rebreather mask, or Venturi mask.	• Withhold LUNSUMIO, manage per current practice guidelines and provide supportive therapy, which may include intensive care. • Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO.[d] • Administer premedication[e] prior to next dose of LUNSUMIO and infuse the next dose at 50% rate. • Hospitalize for the next dose of LUNSUMIO.
		Recurrent Grade 3 CRS • Permanently discontinue LUNSUMIO. • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care.
Grade 4	Fever ≥ 100.4°F (38°C)[c] with: Hypotension requiring multiple vasopressors (excluding vasopressin) and/or hypoxia requiring oxygen by positive pressure (e.g., CPAP, BiPAP, intubation and mechanical ventilation).	• Permanently discontinue LUNSUMIO. • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care.

[a] Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for CRS.
[b] If CRS is refractory to management, consider other causes including hemophagocytic lymphohistiocytosis *[see Warnings and Precautions (5.4)]*.
[c] Premedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.
[d] Refer to Table 2 for information on restarting LUNSUMIO after dose delays *[see Dosage and Administration (2.2)]*.
[e] Refer to Table 3 for additional information on premedication.
[f] Low-flow oxygen defined as oxygen delivered at < 6 L/minute; high-flow oxygen defined as oxygen delivered at ≥ 6 L/minute.

Dosage Modifications for Neurologic Toxicity, including ICANS

Management recommendations for neurologic toxicity, including ICANS, are summarized in Table 5. At the first sign of neurologic toxicity, including ICANS, consider neurology evaluation and withholding of LUNSUMIO based on the type and severity of neurotoxicity. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care.

Table 5. Recommendations for Management of Neurologic Toxicity (including ICANS)

Adverse Reaction	Severity[1,2]	Actions
Neurologic Toxicity[1] (including ICANS[2])	Grade 1	• Continue LUNSUMIO and monitor neurologic toxicity symptoms. • If ICANS, manage per current practice guidelines.
	Grade 2	• Withhold LUNSUMIO until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 72 hours.[3] • Provide supportive therapy, and consider neurologic evaluation. • If ICANS, manage per current practice guidelines.
	Grade 3	• Withhold LUNSUMIO until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 72 hours.[3] • Provide supportive therapy, which may include intensive care, and consider neurology evaluation. • If ICANS, manage per current practice guidelines. • If recurrence of ICANS, permanently discontinue LUNSUMIO.
	Grade 4	• Permanently discontinue LUNSUMIO. • Provide supportive therapy, which may include intensive care, and consider neurology evaluation. • If ICANS, manage per current practice guidelines.

[1] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
[2] Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
[3] See Table 2 for recommendations on restarting LUNSUMIO after dose delays *[see Dosage and Administration (2.2)]*.

Other Adverse Reactions

Table 6. Recommended Dosage Modification for Other Adverse Reactions

Adverse Reactions[1]	Severity[1]	Actions
Infections *[see Warnings and Precautions (5.3)]*	Grades 1 – 4	• Withhold LUNSUMIO in patients with active infection until the infection resolves.[2] • For Grade 4, consider permanent discontinuation of LUNSUMIO.
Neutropenia *[see Warnings and Precautions (5.4)]*	Absolute neutrophil count less than 0.5×10^9/L	• Withhold LUNSUMIO until absolute neutrophil count is 0.5×10^9/L or higher.[2]
Other Adverse Reactions *[see Warnings and Precautions (5.5) and Adverse Reactions (6.1)]*	Grade 3 or higher	• Withhold LUNSUMIO until the toxicity resolves to Grade 1 or baseline.[2]

[1] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
[2] See Table 2 for recommendations on restarting LUNSUMIO after dose delays *[see Dosage and Administration (2.2)]*.

2.5 Preparation and Administration

To prevent medication errors, check the vial labels to ensure that the drug being prepared and administered is LUNSUMIO for intravenous infusion. A peel-off label is provided on the LUNSUMIO Prescribing Information that should be attached to the final prepared solution. Remove the peel-off label from the Prescribing

Information in the LUNSUMIO carton before discarding the carton. Affix the peel-off label to the diluted LUNSUMIO infusion bag.

Preparation

Use aseptic technique to prepare LUNSUMIO.

- Inspect the vial visually for any particulate matter, prior to administration. Do not use if the solution is discolored, or cloudy, or if foreign particles are present.
- Determine the dose, the total volume of LUNSUMIO solution required, and the number of LUNSUMIO vials needed.

Dilution

1. Withdraw the volume from an infusion bag of 0.9% Sodium Chloride Injection, USP or 0.45% Sodium Chloride Injection, USP equal to the volume of the LUNSUMIO required for the patient's dose and discard. Only use infusion bags made of polyvinyl chloride (PVC) or polyolefin (PO) such as polyethylene (PE) and polypropylene (PP).
2. Withdraw the required volume of LUNSUMIO from the vial using a sterile needle and syringe and dilute into the infusion bag of 0.9% Sodium Chloride Injection, USP or 0.45% Sodium Chloride Injection, USP according to Table 7. Discard any unused portion left in the vial.

Table 7. Dilution of LUNSUMIO

Dose of LUNSUMIO	**Volume of LUNSUMIO**	**Size of 0.9% or 0.45% Sodium Chloride Injection Infusion Bag**
1 mg	1 mL	50 mL or 100 mL
2 mg	2 mL	50 mL or 100 mL
60 mg	60 mL	100 mL or 250 mL
30 mg	30 mL	50 mL, 100 mL, or 250 mL

3. Gently mix the intravenous bag by slowly inverting the bag. *Do not shake.*
4. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if visibly opaque particles, discoloration, or foreign particles are observed.
5. Apply the peel-off label from the Prescribing Information to the infusion bag.
6. Immediately use diluted LUNSUMIO infusion solution. If not used immediately, the diluted solution can be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours and at ambient temperature 9°C to 30°C (48°F to 86°F) for up to 16 hours. Prior to administration, ensure the infusion solution comes to reach room temperature.

Administration

- Administer LUNSUMIO as an intravenous infusion only.
- **Do not use an in-line filter to administer LUNSUMIO**.
- Do not mix LUNSUMIO with, or administer through the same infusion line, as other medicinal products.
- No incompatibilities have been observed with infusion sets or infusion aids with product contacting materials of PVC, PE, polyurethane (PUR), polybutadiene (PBD), silicone, acrylonitrile butadiene

styrene (ABS), polycarbonate (PC), polyetherurethane (PEU), fluorinated ethylene propylene (FEP), or polytetrafluorethylene (PTFE), or with drip chamber filter membrane composed of polyamide (PA).

3 DOSAGE FORMS AND STRENGTHS

LUNSUMIO is a sterile, colorless solution for intravenous infusion available as:

- Injection: 1 mg/mL in a single-dose vial
- Injection: 30 mg/30 mL (1 mg/mL) in a single-dose vial

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Cytokine Release Syndrome

LUNSUMIO can cause CRS, including serious or life-threatening reactions *[see Adverse Reactions (6.1)]*.

CRS occurred in 39% of patients who received LUNSUMIO at the recommended dosage in the clinical trial, with Grade 1 CRS occurring in 28%, Grade 2 in 15%, Grade 3 in 2%, and Grade 4 in 0.5% of patients. Among 86 patients who experienced CRS, CRS recurred in 28%. Most cases of CRS occurred following doses of 1 mg on Cycle 1 Day 1 (15%), 2 mg on Cycle 1 Day 8 (5%), and 60 mg on Cycle 1 Day 15 (33%). Five percent of patients experienced CRS after receiving 60 mg on Cycle 2 Day 1 with 1% of patients experiencing CRS following subsequent dosages of LUNSUMIO.

The median time to onset of CRS from the start of administration of LUNSUMIO in Cycle 1 Day 1 was 5 hours (range: 1 hour to 3 days), Cycle 1 Day 8 was 28 hours (range: 5 hours to 3 days), Cycle 1 Day 15 was 25 hours (range: 0.1 hours to 16 days), and Cycle 2 Day 1 was 46 hours (range: 12 hours to 3 days). The median duration of CRS was 3 days (range: 1 to 29 days).

Clinical signs and symptoms of CRS included, but were not limited to, fever, chills, hypotension, tachycardia, hypoxia, and headache. Concurrent neurologic adverse reactions occurred in 6% of patients and included but were not limited to headache, confusional state, and anxiety.

Initiate therapy according to LUNSUMIO step-up dosing schedule to reduce the risk of CRS *[see Dosage and Administration (2.3)]*. Administer pretreatment medications to reduce the risk of CRS, ensure adequate hydration, and monitor patients following administration of LUNSUMIO accordingly.

At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines and administer supportive care; withhold or permanently discontinue LUNSUMIO based on severity *[see Dosage and Administration (2.4)]*.

Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

5.2 Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome

LUNSUMIO can cause serious and life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS) *[see Adverse Reactions (6.1)]*.

Neurologic toxicity occurred in 39% of patients who received LUNSUMIO at the recommended dosage in the clinical trial, with Grade 3 neurologic toxicity occurring in 3% of patients. The most frequent neurologic toxicities were headache (21%), peripheral neuropathy (13%), dizziness (11%) and mental status changes (6%, including confusional state, disturbance in attention, cognitive disorder, delirium, encephalopathy, and somnolence). ICANS was reported in 1% of patients (Grade 1: 0.5%, Grade 2: 0.5%) who received LUNSUMIO at the recommended dosage in the clinical trial.

Across a broader clinical trial population, ICANS or suspected ICANS occurred in 2.2% (21/949) of patients who received LUNSUMIO or LUNSUMIO VELO. The most frequent manifestations included confusional state and lethargy. Twenty patients had Grade 1-2 events and 1 patient had a Grade 3 event. The majority of cases (75%) occurred during the first cycle of treatment. The median time to onset was 17 days (range: 1 to 48 days). In total, 88% of cases resolved after a median duration of 3 days (range: 1 to 20 days).

Coadministration of LUNSUMIO with other products that cause dizziness or mental status changes may increase the risk of neurologic toxicity.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient, consider neurology evaluation as appropriate, and provide supportive therapy based on severity; withhold or permanently discontinue LUNSUMIO based on severity and follow management recommendations *[see Dosage and Administration (2.4)]*.

Patients who experience neurologic toxicity such as tremors, dizziness, insomnia, severe neurotoxicity, or any other adverse reactions that impair consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

5.3 Infections

LUNSUMIO can cause serious or fatal infections *[see Adverse Reactions (6.1)]*.

Among patients who received LUNSUMIO at the recommended dosage in the clinical trial, serious infections, including opportunistic infections, occurred in 17%, with Grade 3 or 4 infections in 14% and fatal infections in 0.9% of patients. The most common Grade 3 or greater infections were pneumonia, sepsis, and upper respiratory infection.

Monitor patients for signs and symptoms of infection prior to and during treatment with LUNSUMIO and treat appropriately. LUNSUMIO should not be administered in the presence of active infection. Caution should be exercised when considering the use of LUNSUMIO in patients with a history of recurring or chronic infections (e.g., chronic, active Epstein-Barr Virus), with underlying conditions that may predispose to infections or who have had significant prior immunosuppressive treatment. Administer prophylactic antimicrobials according to guidelines.

Withhold LUNSUMIO or consider permanent discontinuation of LUNSUMIO based on severity *[see Dosage and Administration (2.4)]*.

5.4 Hemophagocytic Lymphohistiocytosis

LUNSUMIO can cause fatal or serious hemophagocytic lymphohistiocytosis (HLH). HLH is a potentially life-threatening, hyperinflammatory syndrome that is independent of CRS. Common manifestations include fever, elevated ferritin, hemophagocytosis, cytopenias, coagulopathy, hepatitis, and splenomegaly.

Across a broader clinical trial population, HLH occurred in 0.5% (7/1536) of patients. Most cases (5/7) were identified within the first 28 days following initiation of LUNSUMIO or LUNSUMIO VELO, with 3 cases preceded by diagnosed or suspected CRS. Of the 7 cases of HLH, 6 had fatal outcomes, with 2 deaths from HLH alone and 4 deaths with concurrent unresolved HLH. Of the 7 cases of HLH, 4 occurred in the context of concurrent EBV and/or CMV infection.

Monitor for clinical signs and symptoms of HLH. Consider HLH when the presentation of CRS is atypical or prolonged, or when there are features of macrophage activation. For suspected HLH, interrupt LUNSUMIO and evaluate and treat promptly for HLH per current practice guidelines.

5.5 Cytopenias

LUNSUMIO can cause serious or severe cytopenias, including lymphopenia, neutropenia, anemia, and thrombocytopenia *[see Adverse Reactions (6.1)]*.

Among patients who received LUNSUMIO at the recommended dosage in the clinical trial, Grade 3 or 4 decreased lymphocytes occurred in 92%, decreased neutrophils in 38%, decreased hemoglobin in 19%, and decreased platelets in 12% of patients. Grade 4 decreased lymphocytes occurred in 71%, decreased neutrophils in 19%, and decreased platelets in 5% of patients. Febrile neutropenia occurred in 2% of patients.

Monitor complete blood counts throughout treatment. Based on the severity of cytopenias, temporarily withhold, or permanently discontinue LUNSUMIO. Consider prophylactic granulocyte colony-stimulating factor administration as applicable *[see Dosage and Administration (2.4)]*.

5.6 Tumor Flare

LUNSUMIO can cause serious or severe tumor flare *[see Adverse Reactions (6.1)]*.

Among patients who received LUNSUMIO at the recommended dosage in the clinical trial, tumor flare occurred in 4%. Manifestations included new or worsening pleural effusions, localized pain and swelling at the sites of lymphoma lesions, and tumor inflammation.

Patients with bulky tumors or disease located in close proximity to airways or a vital organ should be monitored closely during initial therapy. Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare. If compression or obstruction develops, institute standard treatment of these complications.

5.7 Risk of Medication Errors with Incorrect Product Use

Mosunetuzumab-axgb is available in two formulations: as an injection for intravenous use (LUNSUMIO) and as an injection for subcutaneous use (LUNSUMIO VELO). Check the product labels to ensure that the correct formulation is being prescribed, dispensed, and administered to the patient *[see Dosage and Administration (2.2 and 2.5)]*. Do not substitute LUNSUMIO for or with LUNSUMIO VELO.

5.8 Embryo-Fetal Toxicity

Based on its mechanism of action, LUNSUMIO may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO and for 3 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Cytokine Release Syndrome *[see Warnings and Precautions (5.1)]*
- Neurologic Toxicity, including Immune Effector Cell-associated Neurotoxicity Syndrome *[see Warnings and Precautions (5.2)]*
- Infections *[see Warnings and Precautions (5.3)]*
- Hemophagocytic Lymphohistiocytosis *[see Warnings and Precautions (5.4)]*
- Cytopenias *[see Warnings and Precautions (5.5)]*
- Tumor Flare *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The pooled safety population described in the WARNINGS AND PRECAUTIONS reflects exposure to LUNSUMIO as a single agent in GO29781 in 218 patients with hematologic malignancies in an open-label, multicenter, multi-cohort study. Patients received step-up doses of 1 mg on Cycle 1 Day 1 and 2 mg on Cycle 1 Day 8, followed by 60 mg on Cycle 1 Day 15, and 60 mg on Cycle 2 Day 1, then 30 mg every 3 weeks in

subsequent cycles. Each treatment cycle was 21 days. Among 218 patients who received LUNSUMIO, 52% were exposed for at least 8 cycles and 8% were exposed for 17 cycles.

In this pooled safety population, the most common (≥ 20%) adverse reactions were CRS (39%), fatigue (36%), rash (34%), pyrexia (24%), and headache (21%). The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) were decreased lymphocyte count (92%), decreased phosphate (41%), increased glucose (40%), decreased neutrophil count (38%), decreased hemoglobin (19%), increased uric acid (15%), and decreased platelets (12%).

Relapsed or Refractory Follicular Lymphoma

The safety of LUNSUMIO was evaluated in GO29781, an open-label, multicenter, multi-cohort study which included a cohort of 90 patients with relapsed or refractory follicular lymphoma (FL) *[see Clinical Studies (14)]*. In this cohort, patients with relapsed or refractory FL were required to have received at least two prior lines of systemic therapy, including an anti-CD20 monoclonal antibody and an alkylating agent. Patients received step-up doses of 1 mg on Cycle 1 Day 1 and 2 mg on Cycle 1 Day 8, followed by 60 mg on Cycle 1 Day 15 and 60 mg on Cycle 2 Day 1, then 30 mg every 3 weeks in subsequent cycles. A treatment cycle was 21 days. The median number of cycles was 8 (range: 1 to 17). In the relapsed or refractory FL cohort, 77% were exposed for at least 8 cycles and 12% were exposed for 17 cycles.

The median age was 60 years (range: 29 to 90 years), 61% were male, 82% were White, 4% were Black or African American, 9% were Asian, and 8% were Hispanic or Latino.

Serious adverse reactions occurred in 47% of patients who received LUNSUMIO. Serious adverse reactions in ≥ 2% of patients included CRS, infection (including sepsis, pneumonia, urinary tract infection, EBV viremia, COVID-19, and upper respiratory tract infection), renal insufficiency, pyrexia, and tumor flare.

Permanent discontinuation of LUNSUMIO due to an adverse reaction occurred in 3% of patients. Adverse reactions resulting in permanent discontinuation of LUNSUMIO included CRS and EBV viremia.

Dosage interruptions of LUNSUMIO due to an adverse reaction occurred in 37% of patients. Adverse reactions which required dosage interruption in ≥ 5% of patients included neutropenia, infection, and CRS.

Table 8 summarizes the adverse reactions in patients with relapsed or refractory FL treated with LUNSUMIO in GO29781.

Table 8. Adverse Reactions (≥ 10%) in Patients with Relapsed or Refractory FL Who Received LUNSUMIO Intravenous Infusion in GO29781

Adverse Reaction[1]	LUNSUMIO (N = 90)	
	All Grades (%)	Grade 3 or 4 (%)
Immune system disorders		
Cytokine release syndrome	44	2.2
General disorders and administration site conditions		
Fatigue[2]	42	0
Pyrexia	29	1.1[#]
Edema[3]	17	1.1
Chills	13	1.1[#]
Skin and subcutaneous tissue disorders		
Rash[4]	39	4.4[#]
Pruritus	21	0
Dry skin	16	0
Skin exfoliation	10	0

Adverse Reaction[1]	LUNSUMIO (N = 90)	
	All Grades (%)	Grade 3 or 4 (%)
Nervous system		
Headache[5]	32	1.1[#]
Peripheral neuropathy[6]	20	0
Dizziness[7]	12	0
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[8]	28	1.1[#]
Arthralgia	11	0
Respiratory, thoracic, and mediastinal disorders		
Cough[9]	22	0
Dyspnea[10]	11	1.1[#]
Gastrointestinal disorders		
Diarrhea	17	0
Nausea	17	0
Abdominal pain[11]	12	1.1[#]
Infections		
Upper respiratory tract infection[12]	14	2.2[#]
Urinary tract infection[13]	10	1.1[#]
Psychiatric disorder		
Insomnia	12	0

[1] Adverse reactions were graded based on CTCAE Version 4.0, with the exception of CRS, which was graded per ASTCT 2019 criteria.
[2] Fatigue includes fatigue, asthenia, and lethargy.
[3] Edema includes edema, edema peripheral, peripheral swelling, face edema, swelling face, pulmonary edema, fluid overload, and fluid retention.
[4] Rash includes rash, rash erythematous, exfoliative rash, rash macular, rash maculo-papular, rash papular, rash pruritic, rash pustular, erythema, palmar erythema, dermatitis, and dermatitis acneiform.
[5] Headache includes headache and migraine.
[6] Peripheral neuropathy includes peripheral neuropathy, peripheral sensory neuropathy, paresthesia, dysesthesia, hypoesthesia, burning sensation, and neuralgia.
[7] Dizziness includes dizziness and vertigo.
[8] Musculoskeletal pain includes musculoskeletal pain, back pain, myalgia, musculoskeletal chest pain, and neck pain.
[9] Cough includes cough, productive cough, and upper airway cough syndrome.
[10] Dyspnea includes dyspnea and dyspnea exertional.
[11] Abdominal pain includes abdominal pain, lower abdominal pain, and abdominal discomfort.
[12] Upper respiratory tract infection includes upper respiratory tract infection, nasopharyngitis, sinusitis, and rhinovirus infection.
[13] Urinary tract infection includes urinary tract infection and acute pyelonephritis.
[#] Only Grade 3 adverse reactions occurred.

Clinically relevant adverse reactions in < 10% of patients who received LUNSUMIO included pneumonia, sepsis, COVID-19, EBV viremia, mental status changes, tumor lysis syndrome, renal insufficiency, anxiety, motor dysfunction (including ataxia, gait disturbance and tremor), tumor flare, and ICANS.

Table 9 summarizes the laboratory abnormalities in patients with relapsed or refractory FL treated with LUNSUMIO in GO29781.

Table 9. Select Laboratory Abnormalities (≥ 20%) That Worsened from Baseline in Patients with Relapsed or Refractory FL Who Received LUNSUMIO Intravenous Infusion in GO29781

Laboratory Abnormality	LUNSUMIO[1]	
	All Grades (%)	Grade 3 or 4 (%)
Hematology		
Lymphocyte count decreased	100	98
Hemoglobin decreased	68	12
Neutrophils decreased	58	40
Platelets decreased	46	10
Chemistry		
Phosphate decreased	78	46
Glucose increased	42	42
Aspartate aminotransferase increased	39	4.4
Gamma-glutamyl transferase increased	34	9
Magnesium decreased	34	0
Potassium decreased	33	6
Alanine aminotransferase increased	32	7
Uric acid increased	22	22

[1] The denominator used to calculate the rate varied from 72 to 90 based on the number of patients with a baseline value and at least one post-treatment value.

7 DRUG INTERACTIONS

Effect of LUNSUMIO on CYP450 Substrates

LUNSUMIO causes release of cytokines *[see Clinical Pharmacology (12.2)]* that may suppress activity of CYP450 enzymes, resulting in increased exposure of CYP450 substrates. Increased exposure of CYP450 substrates is more likely to occur after the first dose of LUNSUMIO on Cycle 1 Day 1 and up to 14 days after the 60 mg dose on Cycle 2 Day 1 and during and after CRS *[see Warnings and Precautions (5.1)]*. Monitor for toxicity or concentrations of drugs that are CYP450 substrates where minimal concentration changes may lead to serious adverse reactions. Consult the concomitant CYP450 substrate drug prescribing information for recommended dosage modification.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on the mechanism of action, LUNSUMIO may cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*. There are no available data on the use of LUNSUMIO in pregnant women to evaluate for a drug-associated risk. No animal reproductive or developmental toxicity studies have been conducted with mosunetuzumab-axgb.

Mosunetuzumab-axgb causes T-cell activation and cytokine release; immune activation may compromise pregnancy maintenance. In addition, based on expression of CD20 on B-cells and the finding of B-cell depletion in non-pregnant animals, mosunetuzumab-axgb can cause B-cell lymphocytopenia in infants exposed to mosunetuzumab-axgb in-utero. Human immunoglobulin G (IgG) is known to cross the placenta; therefore, LUNSUMIO has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to the fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% – 4% and 15% – 20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of mosunetuzumab-axgb in human milk, the effect on the breastfed child, or milk production. Because human IgG is present in human milk, and there is potential for mosunetuzumab-axgb absorption leading to B-cell depletion, advise women not to breastfeed during treatment with LUNSUMIO and for 3 months after the last dose.

8.3 Females and Males of Reproductive Potential

LUNSUMIO may cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LUNSUMIO.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO and for 3 months after the last dose.

8.4 Pediatric Use

The safety and efficacy of LUNSUMIO have not been established in pediatric patients.

8.5 Geriatric Use

Among the 90 patients with relapsed or refractory follicular lymphoma treated with LUNSUMIO, 33% were 65 years of age or older, and 8% were 75 years of age or older. There is an insufficient number of patients 65 years of age or older and 75 years of age or older to assess whether there are differences in safety or effectiveness in patients 65 years of age and older compared to younger adult patients.

11 DESCRIPTION

Mosunetuzumab-axgb is a bispecific CD20-directed CD3 T-cell engager. It is a humanized monoclonal anti-CD20xCD3 T-cell-dependent bispecific antibody of the immunoglobulin G1 (IgG1) isotype. Mosunetuzumab-axgb is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology. The approximate molecular weight is 146 kDa.

LUNSUMIO (mosunetuzumab-axgb) injection is a sterile, preservative-free, colorless solution for intravenous use.

Each single-dose vial contains a 1 mL solution of mosunetuzumab-axgb (1 mg), acetic acid (0.4 mg), histidine (1.6 mg), methionine (1.5 mg), polysorbate 20 (0.6 mg), sucrose (82.1 mg), and Water for Injection, USP. The pH is 5.8.

Each single-dose vial contains a 30 mL solution of mosunetuzumab-axgb (30 mg), acetic acid (12.8 mg), histidine (46.6 mg), methionine (44.8 mg), polysorbate 20 (18 mg), sucrose (2,462.4 mg), and Water for Injection, USP. The pH is 5.8.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Mosunetuzumab-axgb is a T-cell engaging bispecific antibody that binds to the CD3 receptor expressed on the surface of T-cells and CD20 expressed on the surface of lymphoma cells and some healthy B-lineage cells.

In vitro, mosunetuzumab-axgb activated T-cells, caused the release of proinflammatory cytokines, and induced lysis of B-cells.

12.2 Pharmacodynamics

After intravenous administration of the recommended dosage of LUNSUMIO, peripheral B-cell counts decreased to undetectable levels (< 5 cells/microliter) in most patients (95%) by Cycle 2 Day 1 and the depletion was sustained at later cycles including at Cycle 4 and Cycle 8.

LUNSUMIO caused hypogammaglobulinemia (defined as IgG levels < 500 mg/dL). Among 67 patients with baseline IgG levels ≥ 500 mg/dL, 40% had their IgG level decreased to < 500 mg/dL after administration of the recommended dosage of LUNSUMIO.

Plasma concentrations of cytokines (IL-2, IL-6, IL-10, TNF-α, and IFN-γ) were measured, and transient elevation of cytokines were observed at doses of 0.4 mg and above. After administration of the recommended dosage of LUNSUMIO, the highest elevation of cytokines was observed within 24 hours after the first dose on Cycle 1 Day 1 and after the first 60 mg dose on Cycle 1 Day 15. The elevated cytokine levels generally returned to baseline prior to the next infusion on Cycle 1 Day 8 and on Cycle 2 Day 1.

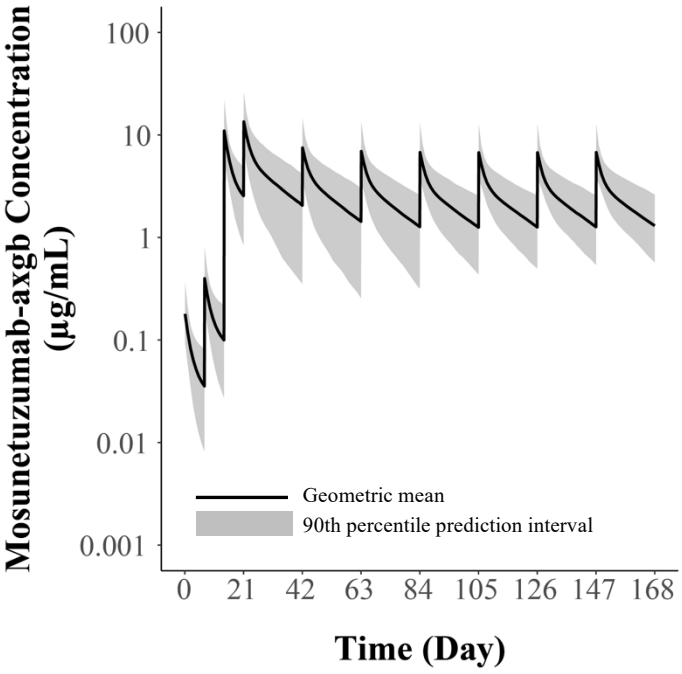
12.3 Pharmacokinetics

Mosunetuzumab-axgb PK exposure increased proportionally over a dose range from 0.2 mg to 60 mg (0.007 to 2 times the recommended treatment dosage). PK exposures for the recommended dosage of LUNSUMIO are summarized in Table 10 and Figure 1.

Table 10. Exposure Parameters of Mosunetuzumab-axgb Intravenous Infusion

	AUC (day•µg/mL)[1]	C_{max} (µg/mL)[1]	C_{trough} (µg/mL)[1]
Cycle 1 (0 – 21 days)	35.2 (36.6)	11.1 (36.7)	2.6 (54.0)
Cycle 2 (21 – 42 days)	90.3 (48.5)	13.6 (37.7)	2.0 (83.1)
Cycle 3 (42 – 63 days)	59.0 (48.9)	7.6 (40.1)	1.4 (75.6)
Steady state[2]	52.9 (40.7)	7.0 (37.9)	1.3 (59.9)
All values reported are model-predicted exposure metrics. [1] Values are geometric mean with geometric CV%. [2] Steady state values are approximated at Cycle 4 (63 – 84 days).			

Figure 1. Model-Predicted Mosunetuzumab-axgb Intravenous Infusion Concentration Time Profile



Pharmacokinetic parameters (Table 11) were evaluated at the recommended dosage and are presented as geometric mean (CV%) unless otherwise specified.

Table 11. Mosunetuzumab-axgb Pharmacokinetic Parameters in Patients with Relapsed or Refractory Follicular Lymphoma

Parameter	LUNSUMIO via Intravenous Infusion
T_{max} median (range), hours[1]	4.0 (4.0 – 4.0)[2]
Volume of distribution[a] (L)	5.5 (31%)
Half-life[a] (days)	16.1 (17%)
Systemic clearance (L/day)	1.1 (63%) at baseline 0.58 (18%) at steady state

T_{max} = time to peak concentration
[1] Steady-state.
[2] T_{max} is at the end of intravenous infusion.

Specific Populations

There were no clinically significant differences in the pharmacokinetics of mosunetuzumab-axgb based on age (19 to 96 years), sex, race (Asian and Non-Asian), ethnicity (Hispanic/Latino and not Hispanic/Latino), mild or moderate renal impairment (estimated creatinine clearance [CrCL] by Cockcroft-Gault formula: 30 to 89 mL/min), or mild hepatic impairment (total bilirubin less than or equal to upper limit of normal [ULN] with AST greater than ULN or total bilirubin greater than 1 to 1.5 times ULN with any AST).

The effects of severe renal impairment (CrCL 15 to 29 mL/min) or moderate to severe hepatic impairment (total bilirubin greater than 1.5 times ULN with any AST) on the pharmacokinetics of mosunetuzumab-axgb are unknown.

Drug Interaction Studies

No clinical studies evaluating the drug interaction potential of mosunetuzumab-axgb have been conducted.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the study described below with the incidence of anti-drug antibodies in other studies, including those of mosunetuzumab-axgb.

During treatment in Study GO29781 (up to 12 months) *[see Clinical Studies (14)]*, using an enzyme-linked immunosorbent assay (ELISA), no patients (N = 418) treated with LUNSUMIO developed anti-mosunetuzumab-axgb antibodies. Based on these data, the clinical relevance of anti-mosunetuzumab-axgb antibodies could not be assessed.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or genotoxicity studies have been conducted with mosunetuzumab-axgb.

No dedicated studies have been conducted to evaluate the effects of mosunetuzumab-axgb on fertility. No adverse effects on either male or female reproductive organs were identified in a 26-week repeat dose chronic toxicity study in sexually mature cynomolgus monkeys.

14 CLINICAL STUDIES

The efficacy of LUNSUMIO was evaluated in an open-label, multicenter, multi-cohort study (GO29781, NCT02500407) in patients with relapsed or refractory follicular lymphoma (FL) who had received at least two prior therapies, including an anti-CD20 monoclonal antibody and an alkylating agent. The study excluded

patients with active infections, history of autoimmune disease, prior allogeneic transplant, or any history of CNS lymphoma or CNS disorders.

Patients received step-up doses of 1 mg on Cycle 1 Day 1 and 2 mg on Cycle 1 Day 8, followed by 60 mg on Cycle 1 Day 15, and 60 mg on Cycle 2 Day 1, then 30 mg via intravenous infusion every 3 weeks in subsequent cycles. A treatment cycle was 21 days. LUNSUMIO was administered for 8 cycles unless patients experienced progressive disease or unacceptable toxicity. After 8 cycles, patients with a complete response discontinued therapy; patients with a partial response or stable disease continued treatment up to 17 cycles, unless patients experienced progressive disease or unacceptable toxicity.

Among the 90 patients with relapsed or refractory FL, the median age was 60 years (range: 29 to 90 years), 33% were 65 years of age or older, 61% were male, 82% were White, 9% were Asian, 4% were Black or African American, and 8% were Hispanic or Latino. A total of 77% of patients had Stage III-IV disease, 34% had bulky disease, and all patients had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. The median number of prior therapies was 3 (range: 2 to 10), with 38% receiving 2 prior therapies, 31% receiving 3 prior therapies, and 31% receiving more than 3 prior therapies.

Seventy-nine percent of patients were refractory to prior anti-CD20 monoclonal antibody therapy, 53% were refractory to both anti-CD20 monoclonal antibody and alkylator therapy, 9% received prior rituximab plus lenalidomide therapy, 21% received prior autologous stem cell transplant, and 3% received prior CAR-T therapy. Fifty-two percent of patients had progression of disease within 24 months of first systemic therapy.

Efficacy was established on the basis of objective response rate (ORR) and duration of response (DOR) as assessed by an independent review facility according to standard criteria for NHL (Cheson 2007). The median follow-up for DOR was 14.9 months. The efficacy results are summarized in Table 12.

Table 12. Efficacy Results in Patients with Relapsed or Refractory FL Who Received LUNSUMIO Intravenous Infusion

Response	**LUNSUMIO N = 90**
Objective response rate (ORR), n (%)	72 (80)
(95% CI)	(70, 88)
Complete response (CR), n (%)	54 (60)
(95% CI)	(49, 70)
Partial response (PR), n (%)	18 (20)
(95% CI)	(12, 30)
Duration of response (DOR)	N = 72
Median DOR[1,2], months (95% CI)	22.8 (10, NR)
Rate of continued response[2]	
At 12 months, %	62
(95% CI)	(50, 74)
At 18 months, %	57
(95% CI)	(44, 70)

CI = confidence interval; NR = not reached
[1] DOR is defined as the time from the initial occurrence of a documented PR or CR until the patient experienced an event (documented disease progression or death due to any cause).
[2] Kaplan-Meier estimate.

The median time to first response was 1.4 months (range: 1.1 to 8.9).

16 HOW SUPPLIED/STORAGE AND HANDLING

LUNSUMIO (mosunetuzumab-axgb) injection is a sterile, colorless, preservative-free solution for intravenous infusion supplied as follows:

- One 1 mg/mL single-dose vial in a carton (NDC 50242-159-01)
- One 30 mg/30 mL (1 mg/mL) single-dose vial in a carton (NDC 50242-142-01).

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
Do not freeze. Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Cytokine Release Syndrome (CRS) – Discuss the signs and symptoms associated with CRS, including fever, chills, hypotension, tachycardia, hypoxia, and headache. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. Advise patients who experience symptoms that impair consciousness not to drive and refrain from operating heavy or potentially dangerous machinery until events resolve *[see Warnings and Precautions (5.1)]*.

Neurologic Toxicity, including ICANS – Discuss the signs and symptoms associated with neurologic toxicity, including ICANS, headache, peripheral neuropathy, dizziness, or mental status changes. Advise patients to immediately contact their healthcare provider if they experience any signs or symptoms of neurologic toxicity. Advise patients who experience neurologic toxicity that impairs consciousness to refrain from driving or operating heavy or potentially dangerous machinery until neurologic toxicity resolves *[see Warnings and Precautions (5.2)]*.

Infections – Discuss the signs or symptoms associated with infection *[see Warnings and Precautions (5.3)]*.

Hemophagocytic Lymphohistiocytosis (HLH) – Discuss the signs and symptoms associated with HLH, including fever, coagulopathy, cytopenias, and splenomegaly *[see Warnings and Precautions (5.4)]*.

Cytopenias – Discuss the signs and symptoms associated with cytopenias, including neutropenia and febrile neutropenia, anemia, and thrombocytopenia *[see Warnings and Precautions (5.5)]*.

Tumor Flare – Inform patients of the potential risk of tumor flare reaction and to report any signs and symptoms associated with this event to their healthcare provider for evaluation *[see Warnings and Precautions (5.6)]*.

Embryo-Fetal Toxicity – Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to inform their healthcare provider if they are pregnant or become pregnant *[see Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO and for 3 months after the last dose *[see Use in Specific Populations (8.3)]*.

Lactation – Advise women not to breastfeed during treatment with LUNSUMIO and for 3 months after the last dose *[see Use in Specific Populations (8.2)]*.

Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990

U.S. License No.: 1048

MEDICATION GUIDE

LUNSUMIO® (lun-SUM-mee-oh)

(mosunetuzumab-axgb)

injection, for intravenous infusion

What is the most important information I should know about LUNSUMIO?

LUNSUMIO may cause Cytokine Release Syndrome (CRS), a serious side effect that is common during treatment with LUNSUMIO, and can also be severe or life-threatening.

Get medical help right away if you develop any signs or symptoms of CRS at any time, including:

- fever of 100.4°F (38°C) or higher
- chills
- low blood pressure
- fast or irregular heartbeat
- tiredness or weakness
- difficulty breathing
- headache
- confusion
- feeling anxious
- dizziness or light-headedness
- nausea
- vomiting

Due to the risk of CRS, you will receive LUNSUMIO on a "step-up dosing schedule".

- The step-up dosing schedule is when you receive smaller "step-up" doses of LUNSUMIO on Day 1 and Day 8 of your first cycle of treatment.
- You will receive a higher dose of LUNSUMIO on Day 15 of your first cycle of treatment.
- If your dose of LUNSUMIO is delayed for any reason, you may need to repeat the "step-up dosing schedule."
- Before each dose in Cycle 1 and Cycle 2, you will receive medicines to help reduce your risk of CRS.
- See **"How will I receive LUNSUMIO?"** for more information about how you will receive LUNSUMIO.

Your healthcare provider will check you for CRS during treatment with LUNSUMIO and may treat you in a hospital if you develop signs and symptoms of CRS. Your healthcare provider may temporarily stop or completely stop your treatment with LUNSUMIO if you have severe side effects.

See **"What are the possible side effects of LUNSUMIO?"** for more information about side effects.

What is LUNSUMIO?

LUNSUMIO is a prescription medicine used to treat adults with follicular lymphoma whose cancer has come back or did not respond to previous treatment, and who have already received two or more treatments for their cancer.

It is not known if LUNSUMIO is safe and effective in children.

Before receiving LUNSUMIO, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had an infusion reaction after receiving LUNSUMIO.
- have an infection or have had an infection in the past which lasted a long time or keeps coming back.
- have or had Epstein-Barr Virus.
- are pregnant or plan to become pregnant. LUNSUMIO may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LUNSUMIO.

  Females who are able to become pregnant:
  - your healthcare provider should do a pregnancy test before you start treatment with LUNSUMIO.
  - you should use an effective method of birth control (contraception) during your treatment and for 3 months after the last dose of LUNSUMIO.
- are breastfeeding or plan to breastfeed. It is not known if LUNSUMIO passes into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of LUNSUMIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive LUNSUMIO?

- LUNSUMIO will be given to you by your healthcare provider by infusion through a needle placed in a vein (intravenous infusion).
- After you complete the weekly "step-up dosing schedule" in Cycle 1, LUNSUMIO is given every 21 days.
- After Cycle 1 and Cycle 2, your healthcare provider will decide if you need to continue to take other medicines to help reduce side effects from LUNSUMIO during future cycles.
- Your healthcare provider will decide how many treatment cycles you will receive of LUNSUMIO.

See **"What is the most important information I should know about LUNSUMIO?"** for more information about how you will receive LUNSUMIO.

What should I avoid while receiving LUNSUMIO?

Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.

See **"What is the most important information I should know about LUNSUMIO?"** and **"What are the possible side effects of LUNSUMIO?"** for more information about signs and symptoms of CRS and neurologic problems.

What are the possible side effects of LUNSUMIO?

LUNSUMIO may cause serious side effects, including:

See **"What is the most important information I should know about LUNSUMIO?"**

- **neurologic problems.** LUNSUMIO can cause serious and life-threatening neurologic problems. Your healthcare provider will check you for neurologic problems during treatment with LUNSUMIO. Your healthcare provider may also refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems during or after treatment with LUNSUMIO, including:
  - headache
  - numbness and tingling of the arms, legs, hands, or feet
  - dizziness
  - confusion and disorientation
  - difficulty paying attention or understanding things
  - forgetting things or forgetting who or where you are
  - trouble speaking, reading, or writing
  - sleepiness or trouble sleeping
  - tremors
  - loss of consciousness
  - seizures
  - muscle problems or muscle weakness
  - loss of balance or trouble walking
  - tiredness
- **serious infections.** LUNSUMIO can cause serious infections that may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with LUNSUMIO, including:
  - fever of 100.4°F (38°C) or higher
  - cough
  - chest pain
  - tiredness
  - shortness of breath
  - painful rash
  - sore throat
  - pain during urination
  - feeling weak or generally unwell
- **hemophagocytic lymphohistiocytosis (HLH).** LUNSUMIO can cause overactivity of the immune system, a condition called hemophagocytic lymphohistiocytosis (HLH). HLH can be life-threatening and has led to death in people treated with LUNSUMIO. Your healthcare provider will check you for HLH especially if your CRS lasts longer than expected. Signs and symptoms of HLH include:
  - fever
  - enlarged spleen
  - easy bruising
  - low blood cell counts
  - liver problems
- **low blood cell counts.** Low blood cell counts are common during treatment with LUNSUMIO and can also be serious or severe.

  Your healthcare provider will check your blood cell counts during treatment with LUNSUMIO. LUNSUMIO can cause the following low blood cell counts:
  - **low white blood cell counts (neutropenia).** Low white blood cells can increase your risk for infection.
  - **low red blood cell counts (anemia).** Low red blood cells can cause tiredness and shortness of breath.
  - **low platelet counts (thrombocytopenia).** Low platelet counts can cause bruising or bleeding problems.

- **growth in your tumor or worsening of tumor related problems (tumor flare).** LUNSUMIO can cause serious or severe worsening of your tumor.

  Tell your healthcare provider if you develop any of these signs or symptoms of tumor flare during your treatment with LUNSUMIO:

  - chest pain
  - cough
  - trouble breathing
  - tender or swollen lymph nodes
  - pain or swelling at the site of the tumor

Your healthcare provider may temporarily stop or permanently stop treatment with LUNSUMIO if you develop severe side effects.

The most common side effects of LUNSUMIO include:

- cytokine release syndrome
- tiredness
- rash
- headache
- fever
- muscle pain
- cough
- itching
- numbness, tingling, or pain in the hands or feet (nerve damage)

The most common severe abnormal blood test results with LUNSUMIO include: decreased blood cell counts, decreased phosphate, increased glucose, and increased uric acid levels.

These are not all the possible side effects of LUNSUMIO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LUNSUMIO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about LUNSUMIO that is written for health professionals.

What are the ingredients in LUNSUMIO?

Active ingredient: mosunetuzumab-axgb

Inactive ingredients: acetic acid, histidine, methionine, polysorbate 20, sucrose, and Water for Injection

Manufactured by: **Genentech, Inc.,** A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No.: 1048

For more information, call 1-844-832-3687 or go to www.LUNSUMIO.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: Dec 2025

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LUNSUMIO VELO safely and effectively. See full prescribing information for LUNSUMIO VELO.

LUNSUMIO VELO™ (mosunetuzumab-axgb) injection, for subcutaneous use
Initial U.S. Approval: 2022

WARNING: CYTOKINE RELEASE SYNDROME
See full prescribing information for complete boxed warning.

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO VELO. Initiate treatment with the LUNSUMIO VELO step-up dosing schedule to reduce the risk of CRS. Withhold LUNSUMIO VELO until CRS resolves or permanently discontinue based on severity. (2.1, 2.4, 5.1)

----------INDICATIONS AND USAGE----------

LUNSUMIO VELO is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). (1.1)

----------DOSAGE AND ADMINISTRATION----------

- **LUNSUMIO VELO and LUNSUMIO have different dosage and route of administration instructions. Administer LUNSUMIO VELO only as a subcutaneous injection. (2.1)**
- Premedicate to reduce risk of CRS. (2.3, 5.1)
- Recommended dosage for LUNSUMIO VELO for subcutaneous injection (2.2):

Day of Treatment [a]		Subcutaneous Dose of LUNSUMIO VELO
Cycle 1	Day 1	5 mg
	Day 8	45 mg
	Day 15	45 mg
Cycles 2+	Day 1	45 mg

[a] Cycle length = 21 days

See Full Prescribing Information for instructions on preparation and administration. (2.5)

----------DOSAGE FORMS AND STRENGTHS----------

Injection:

- 5 mg/0.5 mL solution in a single-dose vial. (3)
- 45 mg/mL solution in a single-dose vial. (3)

----------CONTRAINDICATIONS----------

None. (4)

----------WARNINGS AND PRECAUTIONS----------

- Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome: Can cause serious and life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). Monitor patients for signs and symptoms of neurologic toxicity during treatment; withhold or permanently discontinue based on severity. (5.2)
- Infections**:** Can cause serious or fatal infections. Monitor patients for signs and symptoms of infection, including opportunistic infections, and treat as needed. (5.3)
- Hemophagocytic Lymphohistiocytosis: Can cause serious or fatal reactions. For suspected cases, interrupt LUNSUMIO VELO and evaluate and treat promptly. (5.4)
- Cytopenias: Monitor complete blood cell counts during treatment. (5.5)
- Tumor Flare: Can cause serious tumor flare reactions. Monitor patients at risk for complications of tumor flare. (5.6)
- Risk of Medication Errors with Incorrect Product Use: Ensure that the correct formulation is being prescribed, dispensed, and administered. (5.7)
- Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception. (5.8, 8.1, 8.3)

----------ADVERSE REACTIONS----------

The most common adverse reactions (≥ 20%) are injection site reactions, fatigue, rash, CRS, COVID-19 infection, musculoskeletal pain, and diarrhea.

The most common Grade 3 to 4 laboratory abnormalities (≥ 15%) are decreased lymphocyte count, decreased neutrophil count, and increased uric acid. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 12/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO VELO. Initiate treatment with the LUNSUMIO VELO step-up dosing schedule to reduce the risk of CRS. Withhold LUNSUMIO VELO until CRS resolves or permanently discontinue based on severity *[see Dosage and Administration (2.1 and 2.4) and Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

1.1 Follicular Lymphoma

LUNSUMIO VELO is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate *[see Clinical Studies (14)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing Information

- **LUNSUMIO VELO and LUNSUMIO have different dosage and administration instructions *[see Dosage and Administration (2.2) and Warnings and Precautions (5.7)]*.**
    - **LUNSUMIO VELO is for subcutaneous use only.**
    - **Check the product label to ensure that the correct formulation (LUNSUMIO VELO or LUNSUMIO) is being prescribed and administered.**
    - **Do not substitute LUNSUMIO VELO for or with LUNSUMIO.**
- Administer LUNSUMIO VELO to well-hydrated patients.
- Premedicate before each dose in Cycle 1 *[see Dosage and Administration (2.3)]*.
- LUNSUMIO VELO should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity, including ICANS *[see Warnings and Precautions (5.1 and 5.2)]*.

2.2 Recommended Dosage

The recommended dosage for LUNSUMIO VELO subcutaneous injection is presented in Table 1.

Administer for 8 cycles unless patients experience unacceptable toxicity or disease progression.

For patients who achieve a complete response, no further treatment beyond 8 cycles is required. For patients who achieve a partial response or have stable disease in response to treatment with LUNSUMIO VELO after 8 cycles, an additional 9 cycles of treatment (17 cycles total) should be administered, unless a patient experiences unacceptable toxicity or disease progression.

Table 1. Recommended Dose and Schedule of LUNSUMIO VELO Subcutaneous Injection (21-Day Treatment Cycles)

Day of Treatment		Subcutaneous Dose of LUNSUMIO VELO
Cycle 1	Day 1	5 mg
	Day 8	45 mg
	Day 15	45 mg
Cycles 2+	Day 1	45 mg

Table 2. Recommendations for Restarting Therapy with LUNSUMIO VELO Subcutaneous Injection After Dose Delay

Last Subcutaneous Dose Administered	Time Since Last Dose Administered	Action for Next Subcutaneous Dose(s)
5 mg Cycle 1 Day 1	1 week to 2 weeks	Administer 45 mg (Cycle 1 Day 8)*, then resume the planned treatment schedule.
	Greater than 2 weeks	Repeat 5 mg (Cycle 1 Day 1)*, then administer 45 mg (Cycle 1 Day 8)* and resume the planned treatment schedule.
45 mg Cycle 1 Day 8	1 week to less than 6 weeks	Administer 45 mg (Cycle 1 Day 15)*, then resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 5 mg*, then administer 45 mg (Cycle 1 Day 15)* 7 days later and resume the planned treatment schedule.
45 mg Cycle 1 Day 15	1 week to less than 6 weeks	Administer 45 mg (Cycle 2 Day 1), then resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 5 mg (Cycle 2 Day 1)*, then administer 45 mg (Cycle 2 Day 8)* followed by 45 mg on Day 1 of subsequent cycles.
45 mg Cycle 2 onwards	3 weeks to less than 6 weeks	Administer 45 mg, then resume the planned treatment schedule.
	Greater than or equal to 6 weeks	Repeat 5 mg* on Day 1 during the next cycle, then administer 45 mg* on Day 8, followed by 45 mg on Day 1 of subsequent cycles.
*Administer premedication as per Cycle 1.		

2.3 Recommended Premedication

Premedications to reduce the risk of CRS are outlined in Table 3 *[see Warnings and Precautions (5.1)]*.

Table 3. Premedication to be Administered Prior to LUNSUMIO VELO Subcutaneous Injection

Treatment Cycle	Patients Requiring Premedication	Premedication	Dosage
Cycle 1	All patients	Corticosteroid	Dexamethasone 20 mg (preferred) oral or intravenous or methylprednisolone 80 mg oral or intravenous
		Antihistamine[a]	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or intravenous antihistamine
		Antipyretic[a]	Oral acetaminophen (500 mg to 1,000 mg)
Cycles 2+	Patients who experienced any grade CRS with the previous dose	Corticosteroid	Dexamethasone 20 mg (preferred) oral or intravenous or methylprednisolone 80 mg oral or intravenous
		Antihistamine[a]	Diphenhydramine hydrochloride 50 mg to 100 mg or equivalent oral or intravenous antihistamine
		Antipyretic[a]	Oral acetaminophen (500 mg to 1,000 mg)

[a] Antihistamine and antipyretic premedications are optional in all cycles.

2.4 Dosage Modifications for Adverse Reactions

See Tables 4 and 5 for the recommended dosage modifications for adverse reactions of CRS and neurologic toxicity, including immune effector cell-associated neurotoxicity (ICANS). See Table 6 for the recommended dosage modifications for other adverse reactions following administration of LUNSUMIO VELO.

Dosage Modifications for Cytokine Release Syndrome

Identify CRS based on clinical presentation *[see Warnings and Precautions (5.1)]*. Evaluate for and treat other causes of fever, hypoxia, and hypotension.

If CRS is suspected, withhold LUNSUMIO VELO until CRS resolves, manage according to the recommendations in Table 4 and per current practice guidelines. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS.

Table 4. Recommendations for Management of Cytokine Release Syndrome with LUNSUMIO VELO Subcutaneous Administration

Grade[a]	Presenting Symptoms	Actions[b]
Grade 1	Fever ≥ 100.4°F (38°C)[c]	• Ensure CRS symptoms are resolved prior to the next dose of LUNSUMIO VELO.[d] • Administer premedication[e] prior to next dose of LUNSUMIO VELO and monitor patient more frequently.
Grade 2	Fever ≥ 100.4°F (38°C)[c] with: Hypotension not requiring vasopressors and/or hypoxia requiring low-flow oxygen[f] by nasal cannula or blow-by.	• Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO VELO.[d] • Administer premedication[e] prior to next dose of LUNSUMIO VELO. • For the next dose of LUNSUMIO VELO, monitor more frequently and consider hospitalization.
		Recurrent Grade 2 CRS • Manage per Grade 3 CRS.

Grade[a]	Presenting Symptoms	Actions[b]
Grade 3	Fever ≥ 100.4°F (38°C)[c] with: Hypotension requiring a vasopressor (with or without vasopressin) and/or hypoxia requiring high flow oxygen[f] by nasal cannula, face mask, non-rebreather mask, or Venturi mask.	• Ensure CRS symptoms are resolved for at least 72 hours prior to the next dose of LUNSUMIO VELO.[d] • Administer premedication[e] prior to next dose of LUNSUMIO VELO. • For the next dose of LUNSUMIO VELO, monitor more frequently and hospitalize for the next dose. • If CRS occurred after the 5 mg or 45 mg dose, administer 5 mg as the next dose. Resume treatment schedule after recovery. If the 5 mg dose is tolerated without grade 3 CRS, resume subsequent doses at 45 mg.
		Recurrent Grade 3 CRS • Permanently discontinue LUNSUMIO VELO. • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care.
Grade 4	Fever ≥ 100.4°F (38°C)[c] with: Hypotension requiring multiple vasopressors (excluding vasopressin) and/or hypoxia requiring oxygen by positive pressure (e.g., CPAP, BiPAP, intubation and mechanical ventilation).	• Permanently discontinue LUNSUMIO VELO. • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care.

[a] Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for CRS.
[b] If CRS is refractory to management, consider other causes including hemophagocytic lymphohistiocytosis.
[c] Premedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.
[d] Refer to Table 2 for information on restarting LUNSUMIO VELO after dose delays *[see Dosage and Administration (2.2)]*.
[e] Refer to Table 3 for additional information on premedication.
[f] Low-flow oxygen defined as oxygen delivered at < 6 L/minute; high-flow oxygen defined as oxygen delivered at ≥ 6 L/minute.

Dosage Modifications for Neurologic Toxicity, including ICANS

Management recommendations for neurologic toxicity, including ICANS, are summarized in Table 5. At the first sign of neurologic toxicity, including ICANS, consider neurology evaluation and withholding of LUNSUMIO VELO based on the type and severity of neurotoxicity. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care.

Table 5. Recommendations for Management of Neurologic Toxicity (including ICANS)

Adverse Reaction	Severity[1,2]	Actions
Neurologic Toxicity[1] (including ICANS[2])	Grade 1	• Continue LUNSUMIO VELO and monitor neurologic toxicity symptoms. • If ICANS, manage per current practice guidelines.
	Grade 2	• Withhold LUNSUMIO VELO until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 72 hours.[3] • Provide supportive therapy, and consider neurologic evaluation. • If ICANS, manage per current practice guidelines.
	Grade 3	• Withhold LUNSUMIO VELO until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 72 hours.[3] • Provide supportive therapy, which may include intensive care, and consider neurology evaluation. • If ICANS, manage per current practice guidelines. • If recurrence of ICANS, permanently discontinue LUNSUMIO VELO.
	Grade 4	• Permanently discontinue LUNSUMIO VELO. • Provide supportive therapy, which may include intensive care, and consider neurology evaluation. • If ICANS, manage per current practice guidelines.

[1] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
[2] Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
[3] See Table 2 for recommendations on restarting LUNSUMIO VELO after dose delays *[see Dosage and Administration (2.2)]*.

Other Adverse Reactions

Table 6. Recommended Dosage Modification for Other Adverse Reactions

Adverse Reactions[1]	Severity[1]	Actions
Infections *[see Warnings and Precautions (5.3)]*	Grades 1 – 4	• Withhold LUNSUMIO VELO in patients with active infection until the infection resolves.[2] • For Grade 4, consider permanent discontinuation of LUNSUMIO VELO.
Neutropenia *[see Warnings and Precautions (5.4)]*	Absolute neutrophil count less than 0.5×10^9/L	• Withhold LUNSUMIO VELO until absolute neutrophil count is 0.5×10^9/L or higher.[2]
Other Adverse Reactions *[see Warnings and Precautions (5.5) and Adverse Reactions (6.1)]*	Grade 3 or higher	• Withhold LUNSUMIO VELO until the toxicity resolves to Grade 1 or baseline.[2] • Permanently discontinue LUNSUMIO VELO if a Grade 4 injection site reaction occurs.

[1] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
[2] See Table 2 for recommendations on restarting LUNSUMIO VELO after dose delays *[see Dosage and Administration (2.2)]*.

2.5 Preparation and Administration

If the LUNSUMIO VELO dose is not administered immediately, refer to "Storage of Prepared Syringe" section below.

- To prevent medication errors, check the vial labels to ensure that the drug being prepared and administered is LUNSUMIO VELO for subcutaneous administration. A peel-off label is provided on the LUNSUMIO VELO Prescribing Information that should be attached to the final prepared syringe. Remove the peel-off label from the Prescribing Information in the LUNSUMIO VELO carton before discarding the carton. Affix the peel-off label to the prepared LUNSUMIO VELO syringe.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the solution is discolored, or cloudy, or if foreign particles are present.
- Each LUNSUMIO VELO 5 mg/0.5 mL and 45 mg/mL vial are supplied as ready-to-use solution that do not need dilution prior to subcutaneous administration. LUNSUMIO VELO vials are for one-time use in one patient only.
- No incompatibilities between LUNSUMIO VELO and polypropylene or polycarbonate syringe material, stainless-steel transfer and injection needles, and polyethylene or polypropylene syringe closing caps have been observed.

Preparation of the Syringe

- Use aseptic technique to prepare LUNSUMIO VELO.
- Select the appropriate strength vial based on the prescribed dose.
- Withdraw the required volume of LUNSUMIO VELO solution from the vial with a syringe and an appropriately sized transfer needle (18G to 21G recommended). The smallest syringe that can accurately deliver the injection volume should be used. Discard any unused portion left in the vial.
- Remove the transfer needle and attach an appropriately sized injection needle (25G to 30G recommended).
- Apply peel-off label from the Prescribing Information to the prepared drug product.
- Once transferred from the vial to the syringe, LUNSUMIO VELO solution for injection should be injected immediately because LUNSUMIO VELO solution for injection does not contain any antimicrobial-preservative.

Administration

Inject the required volume of LUNSUMIO VELO into the subcutaneous tissue of the abdomen or thigh, changing the site of injection with each dose. Do not inject into tattoos, moles, scars or areas where the skin is red, bruised, tender, hard, or not intact. The dose should be administered subcutaneously over approximately 30 seconds to 1 minute.

Storage of Prepared Syringe

- The prepared syringe should be used immediately. If not used immediately, replace the transfer needle with a syringe closing cap. Do not attach an injection needle.
- The capped syringe can be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 32 hours protected from light and/or at 9°C to 25°C (37°F to 77°F) for up to 8 hours at ambient light.
- Once removed from refrigerated storage, the solution can be equilibrated to ambient temperature up to 25°C (77°F) prior to administration. Do not warm LUNSUMIO VELO in any other way.

3 DOSAGE FORMS AND STRENGTHS

LUNSUMIO VELO is a sterile, colorless to slightly brownish-yellow solution for subcutaneous injection available as:

- Injection: 5 mg/0.5 mL in a single-dose vial
- Injection: 45 mg/mL in a single-dose vial

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Cytokine Release Syndrome

LUNSUMIO VELO can cause CRS, including serious or life-threatening reactions *[see Adverse Reactions (6.1)]*.

CRS occurred in 30% of patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial (N = 94), with Grade 1 CRS occurring in 20%, Grade 2 in 7%, and Grade 3 in 2.1% of patients. Among 28 patients who experienced CRS, CRS recurred in 14%. CRS occurred most commonly after the first two doses: 19% of patients experienced CRS after the Cycle 1 Day 1 dose, 13% after the Cycle 1 Day 8 dose, and 2.1% after the Cycle 1 Day 15 dose.

The median time to CRS onset from the start of LUNSUMIO VELO administration was 17 hours (range: 7 to 33 hours) with the Cycle 1 Day 1 dose, and 62 hours (range: 30 to 113 hours) with the Cycle 1 Day 8 dose. CRS resolved in all patients, after a median duration of 2 days (range: 1 to 15 days).

Clinical signs and symptoms of CRS included fever, hypotension, hypoxia, chills, tachycardia, and headache. Concurrent neurologic adverse reactions occurred in 5% of patients and included but were not limited to headache, dizziness, lethargy, memory impairment, and peripheral neuropathy.

Initiate therapy according to LUNSUMIO VELO step-up dosing schedule to reduce the risk of CRS *[see Dosage and Administration (2.3)]*. Administer pretreatment medications to reduce the risk of CRS, ensure adequate hydration, and monitor patients following administration of LUNSUMIO VELO accordingly.

At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care; withhold or permanently discontinue LUNSUMIO VELO based on severity *[see Dosage and Administration (2.4)]*.

Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

5.2 Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome

LUNSUMIO VELO can cause serious and life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS) *[see Adverse Reactions (6.1)]*.

Neurologic toxicity occurred in 53% of patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial (N = 94), with Grade 3 neurologic toxicity occurring in 1.1% of patients. The most frequent neurologic toxicities were headache (17%), insomnia (15%), dizziness (10%), and mental status changes (7%, including confusion and lethargy). ICANS or suspected ICANS was reported in 3.1% of patients (all Grade 1).

Across a broader clinical trial population, ICANS or suspected ICANS occurred in 2.2% (21/949) of patients who received LUNSUMIO or LUNSUMIO VELO. The most frequent manifestations included confusional state and lethargy. Twenty patients had Grade 1-2 reactions and 1 patient had a Grade 3 event. The majority of

cases (75%) occurred during the first cycle of treatment. The median time to onset was 17 days (range: 1 to 48 days). In total, 88% of cases resolved after a median duration of 3 days (range: 1 to 20 days).

Coadministration of LUNSUMIO VELO with other products that cause dizziness or mental status changes may increase the risk of neurologic toxicity.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient, consider neurology evaluation as appropriate, and provide supportive therapy based on severity; withhold or permanently discontinue LUNSUMIO VELO based on severity and follow management recommendations *[see Dosage and Administration (2.4)]*.

Patients who experience neurologic toxicity such as tremors, dizziness, insomnia, severe neurotoxicity, or any other adverse reactions that impair consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

5.3 Infections

LUNSUMIO VELO can cause serious or fatal infections *[see Adverse Reactions (6.1)]*.

Among patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial, serious infections, including opportunistic infections, occurred in 17%, with Grade 3 or 4 infections in 16% and fatal infections in 3.2% of patients. The most common Grade 3 or greater infections were pneumonia, sepsis, and COVID-19.

Monitor patients for signs and symptoms of infection prior to and during treatment with LUNSUMIO VELO and treat appropriately. LUNSUMIO VELO should not be administered in the presence of active infection. Caution should be exercised when considering use in patients with a history of recurring or chronic infections (e.g., chronic, active Epstein-Barr Virus), with underlying conditions that may predispose to infections or who have had significant prior immunosuppressive treatment. Administer prophylactic antimicrobials according to guidelines.

Withhold LUNSUMIO VELO or consider permanent discontinuation based on severity *[see Dosage and Administration (2.4)]*.

5.4 Hemophagocytic Lymphohistiocytosis

LUNSUMIO VELO can cause fatal or serious hemophagocytic lymphohistiocytosis (HLH). HLH is a potentially life-threatening, hyperinflammatory syndrome that is independent of CRS. Common manifestations include fever, elevated ferritin, hemophagocytosis, cytopenias, coagulopathy, hepatitis, and splenomegaly.

Across a broader clinical trial population, HLH occurred in 0.5% (7/1536) of patients who received LUNSUMIO or LUNSUMIO VELO. Most cases (5/7) were identified within the first 28 days following initiation of treatment, with 3 cases preceded by diagnosed or suspected CRS. Of the 7 cases of HLH, 6 had fatal outcomes, with 2 deaths from HLH alone and 4 deaths with concurrent unresolved HLH. Of the 7 cases of HLH, 4 occurred in the context of concurrent EBV and/or CMV infection.

Monitor for clinical signs and symptoms of HLH. Consider HLH when the presentation of CRS is atypical or prolonged, or when there are features of macrophage activation. For suspected HLH, interrupt LUNSUMIO VELO and evaluate and treat promptly for HLH per current practice guidelines.

5.5 Cytopenias

LUNSUMIO VELO can cause serious or severe cytopenias, including lymphopenia, neutropenia, anemia, and thrombocytopenia *[see Adverse Reactions (6.1)]*.

Among patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial (N = 94), Grade 3 or 4 decreased lymphocytes occurred in 69%, decreased neutrophils occurred in 26%, decreased hemoglobin in 10%, and decreased platelets in 6% of patients. Grade 4 decreased lymphocytes occurred in

22%, decreased neutrophils in 9% and decreased platelets in 3.2% of patients. Febrile neutropenia occurred in 2.1% of patients.

Monitor complete blood counts throughout treatment. Based on the severity of cytopenias, temporarily withhold, or permanently discontinue LUNSUMIO VELO. Consider prophylactic granulocyte colony-stimulating factor administration as applicable *[see Dosage and Administration (2.4)]*.

5.6 Tumor Flare

LUNSUMIO VELO can cause serious or severe tumor flare *[see Adverse Reactions (6.1)]*.

Among patients who received LUNSUMIO VELO at the recommended dosage in the clinical trial (N = 94), tumor flare occurred in 1.1% of patients. Manifestations may include new or worsening pleural effusions, localized pain and swelling at the sites of lymphoma lesions, and tumor inflammation.

Patients with bulky tumors or disease located in close proximity to airways or a vital organ should be monitored closely during initial therapy. Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare. If compression or obstruction develops, institute standard treatment of these complications.

5.7 Risk of Medication Errors with Incorrect Product Use

Mosunetuzumab-axgb is available in two formulations: as an injection for subcutaneous use (LUNSUMIO VELO) and an injection for intravenous use (LUNSUMIO). Check the product labels to ensure that the correct formulation is being prescribed, dispensed, and administered to the patient *[see Dosage and Administration (2.2 and 2.5)]*. Do not substitute LUNSUMIO VELO for or with LUNSUMIO.

5.8 Embryo-Fetal Toxicity

Based on its mechanism of action, LUNSUMIO VELO may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO VELO and for 3 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Cytokine Release Syndrome *[see Warnings and Precautions (5.1)]*
- Neurologic Toxicity, including Immune Effector Cell-associated Neurotoxicity Syndrome *[see Warnings and Precautions (5.2)]*
- Infections *[see Warnings and Precautions (5.3)]*
- Hemophagocytic Lymphohistiocytosis *[see Warnings and Precautions (5.4)]*
- Cytopenias *[see Warnings and Precautions (5.5)]*
- Tumor Flare *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Relapsed or Refractory Follicular Lymphoma

The safety of LUNSUMIO VELO was evaluated in an open-label, multicenter study which included a cohort of 94 patients with relapsed or refractory follicular lymphoma (FL) after at least two lines of systemic therapy *[see Clinical Studies (14)]*. Patients received step-up doses of 5 mg via subcutaneous injection on Cycle 1 Day 1 and 45 mg on Cycle 1 Day 8, followed by 45 mg on Cycle 1 Day 15, then 45 mg every 3 weeks in subsequent

cycles. A treatment cycle was 21 days. The median number of cycles was 8 (range: 1 to 17), with 78% of patients exposed for at least 8 cycles and 6% exposed for 17 cycles.

The median age was 65 years (range: 35 to 84 years), 56% were male, 85% were White, 2.1% were Black or African American, 11% were Asian, and 2% were Hispanic or Latino.

Serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥ 10% of patients included infection (17%, including pneumonia, other respiratory tract infections, and sepsis) and CRS (15%). Fatal adverse reactions occurred in 4.3% of patients from COVID-19 (3.2%) and HLH (1.1%).

Permanent discontinuation LUNSUMIO VELO due to an adverse reaction occurred in 7% of patients, including from COVID-19.

Dosage interruptions of LUNSUMIO VELO due to an adverse reaction occurred in 40% of patients. Adverse reactions which required dosage interruption in ≥ 5% of patients included COVID-19 and neutropenia.

The most common adverse reactions (≥ 20%), excluding laboratory abnormalities, were injection site reactions, fatigue, rash, CRS, COVID-19 infection, musculoskeletal pain, and diarrhea. The most common Grade 3-4 laboratory abnormalities (≥ 15%) were decreased lymphocyte count, decreased neutrophil count, and increased uric acid. Grade 4 laboratory abnormalities in > 5% included lymphocyte count decreased (22%) and neutrophil count decreased (9%).

Table 7 summarizes the adverse reactions.

Table 7. Adverse Reactions (≥ 10%) in Patients with Relapsed or Refractory FL Who Received LUNSUMIO VELO Subcutaneous Injection in GO29781

Adverse Reaction	LUNSUMIO VELO (N = 94)	
	All Grades (%)	Grade 3 or 4 (%)
Immune system disorders		
Cytokine release syndrome	30	2.1
General disorders and administration site conditions		
Injection site reactions[1]	69	0
Fatigue[2]	39	0
Edema[3]	13	0
Pyrexia	11	1.1
Chills	11	0
Skin and subcutaneous tissue disorders		
Rash[4]	35	3.2
Dry skin	11	0
Nervous system		
Headache	17	0
Peripheral neuropathy[5]	11	0
Dizziness[6]	10	0
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[7]	20	0
Arthralgia	13	0
Respiratory, thoracic, and mediastinal disorders		
Cough	13	0
Dyspnea	11	0
Gastrointestinal disorders		
Diarrhea	20	0
Nausea	14	0
Constipation	14	0
Abdominal pain	13	0
Infections		
COVID-19[*,§]	27	4.3

Adverse Reaction	LUNSUMIO VELO (N = 94)	
	All Grades (%)	Grade 3 or 4 (%)
Upper respiratory tract infection[8]	15	2.1
Pneumonia[9]	13	4.3
Psychiatric disorder		
Insomnia	15	0

The table includes a combination of grouped and ungrouped terms. Adverse reactions were graded based on CTCAE Version 4.0, with the exception of CRS, which was graded per ASTCT 2019 criteria.
* Adverse reaction with fatal outcome.
§ Grade 5 COVID-19 occurred in 3.2% of patients.
1 Injection site reactions includes injection site reaction, injection site discharge, injection site erythema, injection site edema, injection site pain, injection site pruritus and injection site rash.
2 Fatigue includes fatigue, asthenia, and lethargy.
3 Edema includes edema, edema peripheral, face edema, pulmonary edema, fluid overload, and related terms.
4 Rash includes rash, injection site rash, erythema, dermatitis, palmar-plantar erythrodysesthesia, erythema multiforme, urticaria, and related terms.
5 Peripheral neuropathy includes peripheral neuropathy, peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, dysesthesia, hypoesthesia, burning sensation, and neuralgia.
6 Dizziness includes dizziness and vertigo.
7 Musculoskeletal pain includes musculoskeletal pain, back pain, myalgia, musculoskeletal chest pain, and neck pain.
8 Upper respiratory tract infection includes upper respiratory tract infection, nasopharyngitis, sinusitis, rhinovirus infection, and related terms.
9 Pneumonia includes lung consolidation and specific types of pneumonia including COVID-19 pneumonia.

Clinically relevant adverse reactions in < 10% of patients who received LUNSUMIO VELO included pruritus, skin exfoliation, herpes zoster infection, tremor, sepsis, cytomegalovirus (CMV) infection, ICANS, febrile neutropenia, capillary leak syndrome, tumor flare, and HLH .

Table 8 summarizes select laboratory abnormalities.

Table 8. Select Laboratory Abnormalities (≥ 20%) That Worsened from Baseline in Patients with Relapsed or Refractory FL Who Received LUNSUMIO VELO Subcutaneous Injection in GO29781

Laboratory Abnormality	LUNSUMIO VELO[1]	
	All Grades (%)	Grade 3 or 4 (%)
Hematology		
Lymphocyte count decreased	84	69
Hemoglobin decreased	60	10
Neutrophils decreased	50	26
Platelets decreased	33	6.4
Chemistry		
Phosphate decreased	48	11
Alanine aminotransferase increased	34	1.1
Gamma-glutamyl transferase increased	31	1.1
Uric acid increased	28	28
Aspartate aminotransferase increased	28	2.1
Potassium decreased	27	0
Magnesium decreased	25	2.1

[1] The denominator used to calculate the rate varied from 85 to 94 based on the number of patients with a baseline value and at least one post-treatment value.

Clinically relevant laboratory abnormalities in < 20% of patients included glucose increased.

7 DRUG INTERACTIONS

Effect of LUNSUMIO VELO on CYP450 Substrates

LUNSUMIO VELO causes release of cytokines *[see Clinical Pharmacology (12.2)]* that may suppress activity of CYP450 enzymes, resulting in increased exposure of CYP450 substrates. Increased exposure of CYP450 substrates is more likely to occur after the first dose of LUNSUMIO VELO on Cycle 1 Day 1 and up to 14 days after the 45 mg dose on Cycle 1 Day 8 and during and after CRS *[see Warnings and Precautions (5.1)]*. Monitor for toxicity or concentrations of drugs that are CYP450 substrates where minimal concentration changes may lead to serious adverse reactions. Consult the concomitant CYP450 substrate drug prescribing information for recommended dosage modification.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on the mechanism of action, LUNSUMIO VELO may cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*. There are no available data on the use of LUNSUMIO VELO in pregnant women to evaluate for a drug-associated risk. No animal reproductive or developmental toxicity studies have been conducted with mosunetuzumab-axgb.

Mosunetuzumab-axgb causes T-cell activation and cytokine release; immune activation may compromise pregnancy maintenance. In addition, based on expression of CD20 on B-cells and the finding of B-cell depletion in non-pregnant animals, mosunetuzumab-axgb can cause B-cell lymphocytopenia in infants exposed to mosunetuzumab-axgb in-utero. Human immunoglobulin G (IgG) is known to cross the placenta; therefore, LUNSUMIO VELO has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to the fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% – 4% and 15% – 20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of mosunetuzumab-axgb in human milk, the effect on the breastfed child, or milk production. Because human IgG is present in human milk, and there is potential for mosunetuzumab-axgb absorption leading to B-cell depletion, advise women not to breastfeed during treatment with LUNSUMIO VELO and for 3 months after the last dose.

8.3 Females and Males of Reproductive Potential

LUNSUMIO VELO may cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LUNSUMIO VELO.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO VELO and for 3 months after the last dose.

8.4 Pediatric Use

The safety and efficacy of LUNSUMIO VELO have not been established in pediatric patients.

8.5 Geriatric Use

Among the 94 patients treated with LUNSUMIO VELO, 51% were 65 years of age or older. There is an insufficient number of patients 65 years of age or older to assess whether there are differences in safety or effectiveness by age group.

11 DESCRIPTION

Mosunetuzumab-axgb is a bispecific CD20-directed CD3 T-cell engager. It is a humanized monoclonal anti-CD20xCD3 T-cell-dependent bispecific antibody of the immunoglobulin G1 (IgG1) isotype. Mosunetuzumab-axgb is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology. The approximate molecular weight is 146 kDa.

LUNSUMIO VELO (mosunetuzumab-axgb) injection is a sterile, preservative-free, colorless to slightly brownish-yellow solution for subcutaneous use.

Each single-dose vial contains a 0.5 mL solution of mosunetuzumab-axgb (5 mg), acetic acid (0.2 mg), histidine (0.8 mg), methionine (0.7 mg), polysorbate 20 (0.3 mg), sucrose (41 mg), and Water for Injection, USP. The pH is 5.8.

Each single-dose vial contains a 1 mL solution of mosunetuzumab-axgb (45 mg), acetic acid (0.4 mg), histidine (1.6 mg), methionine (1.5 mg), polysorbate 20 (0.6 mg), sucrose (82.1 mg), and Water for Injection, USP. The pH is 5.8.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Mosunetuzumab-axgb is a T-cell engaging bispecific antibody that binds to the CD3 receptor expressed on the surface of T-cells and CD20 expressed on the surface of lymphoma cells and some healthy B-lineage cells.

In vitro, mosunetuzumab-axgb activated T-cells, caused the release of proinflammatory cytokines, and induced lysis of B-cells.

12.2 Pharmacodynamics

After subcutaneous administration of the recommended dosage of LUNSUMIO VELO, peripheral B-cell counts decreased to undetectable levels (< 5 cells/microliter) in most patients (94%) by Cycle 2 Day 1 and the depletion was sustained at later cycles including at Cycle 4 and Cycle 8.

LUNSUMIO VELO caused hypogammaglobulinemia (defined as IgG levels < 500 mg/dL). Among 49 patients with baseline IgG levels ≥ 500 mg/dL, 39% experienced a decrease in their IgG levels to < 500 mg/dL after receiving LUNSUMIO VELO.

Plasma concentrations of cytokines (IL-2, IL-6, IL-10, TNF-α and IFN-γ) were measured with subcutaneous administration of LUNSUMIO VELO, and transient elevation of cytokines were observed at doses of 1.6 mg and above. After administration of the recommended dosage of LUNSUMIO VELO, the highest elevation of cytokines was generally observed within 48 hours after the first dose on Cycle 1 Day 8 and generally returned to baseline prior to the third 45 mg full dose on Cycle 2 Day 1. The observed pattern of cytokine release appeared slower and reduced relative to intravenous administration.

12.3 Pharmacokinetics

Mosunetuzumab-axgb subcutaneously administered PK exposure increased proportionally over a dose range from 1.6 mg to 45 mg (0.04 to 1 times the recommended treatment dosage).

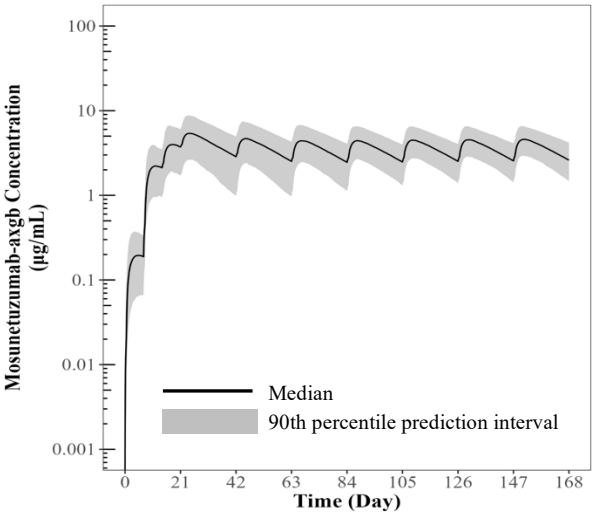
When comparing mosunetuzumab exposures following the recommended LUNSUMIO VELO subcutaneous dosing regimen to the recommended LUNSUMIO intravenous dosing regimen in patients with relapsed or refractory follicular lymphoma in Study GO29781 *[see Clinical Studies (14)]*, the geometric mean ratios (GMRs) (90% CI) for observed Cycle 3 C_{trough} was 1.39 (1.20 to 1.61) and AUC over 0-84 days was 1.06 (0.92

to 1.21). PK exposures for the recommended dosage of LUNSUMIO VELO via subcutaneous injection are summarized in Table 9 and Figure 1.

Table 9. Exposure Parameters of Mosunetuzumab-axgb Subcutaneous Injection

	AUC (day•µg/mL)[1]	C_{max} (µg/mL)[1]	C_{trough} (µg/mL)[1]
Cycle 1 (0 – 21 days)	36.7 (57.0)	3.8 (53.9)	3.5 (54.1)
Cycle 2 (21 – 42 days)	82.3 (50.9)	5.2 (50.3)	2.5 (55.7)
Cycle 3 (42 – 63 days)	72.9 (42.8)	4.5 (44.0)	2.4 (52.3)
Steady state[2]	72.8 (34.5)	4.4 (36.7)	2.4 (34.2)
All values reported are model-predicted exposure metrics. [1] Values are geometric mean with geometric CV%. [2] Steady state values are approximated at Cycle 4 (63 – 84 days).			

Figure 1. Model-Predicted Mosunetuzumab-axgb Subcutaneous Injection Concentration Time Profile



Pharmacokinetic parameters (Table 10) were evaluated at the recommended dosage and are presented as geometric mean (CV%) unless otherwise specified.

Table 10. Mosunetuzumab-axgb Pharmacokinetic Parameters in Patients with Relapsed or Refractory Follicular Lymphoma

Parameter	LUNSUMIO VELO via Subcutaneous Infusion
Bioavailability	89.8%
T_{max} median (range), days[1]	4.2 (2.5 – 7.1)
Volume of distribution[a] (L)	5.5 (31%)
Half-life[a] (days)	17.0 (15%)
Systemic clearance (L/day)	1.1 (63%) at baseline 0.58 (18%) at steady state
T_{max} = time to peak concentration [1] Steady-state	

Specific Populations

There were no clinically significant differences in the pharmacokinetics of mosunetuzumab-axgb based on age (18 to 96 years), sex, race (Asian and Non-Asian), ethnicity (Hispanic/Latino and not Hispanic/Latino), mild or

moderate renal impairment (estimated creatinine clearance [CrCL] by Cockcroft-Gault formula: 30 to 89 mL/min), or mild hepatic impairment (total bilirubin less than or equal to upper limit of normal [ULN] with AST greater than ULN or total bilirubin greater than 1 to 1.5 times ULN with any AST).

The effects of severe renal impairment (CrCL 15 to 29 mL/min) or moderate to severe hepatic impairment (total bilirubin greater than 1.5 times ULN with any AST) on the pharmacokinetics of mosunetuzumab-axgb are unknown.

Drug Interaction Studies

No clinical studies evaluating the drug interaction potential of mosunetuzumab-axgb have been conducted.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the study described below with the incidence of anti-drug antibodies in other studies, including those of mosunetuzumab-axgb.

During treatment in Study GO29781 (up to 12 months) *[see Clinical Studies (14)]*, using an enzyme-linked immunosorbent assay (ELISA), no patients (N = 216) treated with LUNSUMIO VELO monotherapy developed anti-mosunetuzumab-axgb antibodies. Based on these data, the clinical relevance of anti-mosunetuzumab-axgb antibodies could not be assessed.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or genotoxicity studies have been conducted with mosunetuzumab-axgb.

No dedicated studies have been conducted to evaluate the effects of mosunetuzumab-axgb on fertility. No adverse effects on either male or female reproductive organs were identified in a 26-week repeat dose chronic toxicity study in sexually mature cynomolgus monkeys.

14 CLINICAL STUDIES

The efficacy of LUNSUMIO VELO was evaluated in an open-label, multicenter, multi-cohort study (GO29781, NCT02500407) in patients with relapsed or refractory FL after at least two lines of systemic therapy, including an anti-CD20 monoclonal antibody and an alkylating agent. The study excluded patients with active infections, history of autoimmune disease, prior allogeneic transplant, or any history of central nervous system (CNS) lymphoma or CNS disorders.

Patients received 5 mg on Cycle 1 Day 1 and 45 mg on Cycle 1 Day 8, followed by 45 mg on Cycle 1 Day 15, then 45 mg via subcutaneous injection every 3 weeks in subsequent cycles. A treatment cycle was 21 days. LUNSUMIO VELO was administered for 8 cycles unless patients experienced progressive disease or unacceptable toxicity. After 8 cycles, patients with a complete response discontinued therapy; patients with a partial response or stable disease continued treatment up to 17 cycles, unless patients experienced progressive disease or unacceptable toxicity.

Among the 94 patients, the median age was 65 years (range: 35 to 84) with 49% being age > 65; 56% were male; 85% were White, 11% Asian, 2% Black, and 2% Hispanic or Latino. All had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. The median number of prior lines of systemic therapy was 3 (range: 2 to 9), with 47% receiving 2 prior lines, 19% receiving 3 prior lines, and 34% receiving 4 or more prior lines.

Sixty-seven percent of patients had refractory disease to prior anti-CD20 monoclonal antibody therapy, 46% had refractory disease to both an anti-CD20 monoclonal antibody and alkylator, 20% had prior autologous stem cell transplant, 16% had prior rituximab plus lenalidomide, and 4% had prior CAR-T therapy. Twenty-five percent had bulky disease, and 44% had progression of disease within 24 months of first systemic therapy.

Efficacy was established on the basis of objective response rate (ORR) and duration of response (DOR) as assessed by an independent review facility using 2007 International Working Group criteria. Efficacy results are summarized in Table 11. The median follow-up for DOR was 16.0 months.

Table 11. Efficacy Results in Patients with Relapsed or Refractory FL Who Received LUNSUMIO VELO Subcutaneous Injection

Response	LUNSUMIO VELO N=94
Objective response rate, n (%)	70 (75)
(95% CI)	(64, 83)
Complete response, n (%)	55 (59)
(95% CI)	(48, 69)
Partial response, n (%)	15 (16)
(95% CI)	(9, 25)
Duration of response[1,2]	N = 70
Median DOR[2], months (95% CI)	22.4 (16.8, 22.8)
Rate of continued response[2]	
At 12 months,%	70
(95% CI)	(59, 81)
At 18 months, %	60
(95% CI)	(46, 73)

DOR = duration of response; CI = confidence interval
[1] DOR is defined as time from first documented PR or CR to documented disease progression or death due to any cause.
[2] Kaplan-Meier estimate.

The median time to first response was 2.8 months (range: 1.2 to 16.0).

16 HOW SUPPLIED/STORAGE AND HANDLING

LUNSUMIO VELO (mosunetuzumab-axgb) injection is a sterile, colorless to slightly brownish-yellow, preservative-free solution for subcutaneous injection supplied as follows:

- One 5 mg/0.5 mL single-dose vial in a carton (NDC 50242-177-01)
- One 45 mg/mL single-dose vial in a carton (NDC 50242-201-01).

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
Do not freeze. Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Cytokine Release Syndrome (CRS) – Discuss the signs and symptoms associated with CRS, including fever, chills, hypotension, tachycardia, hypoxia, and headache. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. Advise patients who experience symptoms that impair consciousness not to drive and refrain from operating heavy or potentially dangerous machinery until events resolve *[see Warnings and Precautions (5.1)]*.

Neurologic Toxicity, including ICANS – Discuss the signs and symptoms associated with neurologic toxicity, including ICANS, headache, peripheral neuropathy, dizziness, or mental status changes. Advise patients to immediately contact their healthcare provider if they experience any signs or symptoms of neurologic toxicity. Advise patients who experience neurologic toxicity that impairs consciousness to refrain from driving or operating heavy or potentially dangerous machinery until neurologic toxicity resolves *[see Warnings and Precautions (5.2)]*.

Infections – Discuss the signs or symptoms associated with infection *[see Warnings and Precautions (5.3)]*.

Hemophagocytic Lymphohistiocytosis (HLH) – Discuss the signs and symptoms associated with HLH, including fever, coagulopathy, cytopenias, and splenomegaly *[see Warnings and Precautions (5.4)]*.

Cytopenias – Discuss the signs and symptoms associated with cytopenias, including neutropenia and febrile neutropenia, anemia, and thrombocytopenia *[see Warnings and Precautions (5.5)]*.

Tumor Flare – Inform patients of the potential risk of tumor flare reaction and to report any signs and symptoms associated with this event to their healthcare provider for evaluation *[see Warnings and Precautions (5.6)]*.

Injection-Site Reactions – Inform patients that injection site reactions may occur and to report any severe reactions *[See Adverse Reactions (6.1)]*.

Embryo-Fetal Toxicity – Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to inform their healthcare provider if they are pregnant or become pregnant *[see Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO VELO and for 3 months after the last dose *[see Use in Specific Populations (8.3)]*.

Lactation – Advise women not to breastfeed during treatment with LUNSUMIO VELO and for 3 months after the last dose *[see Use in Specific Populations (8.2)]*.

Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990

U.S. License No.: 1048

MEDICATION GUIDE

LUNSUMIO VELO™ (lun-SUM-mee-oh VEH-low)

(mosunetuzumab-axgb)

injection, for subcutaneous use

What is the most important information I should know about LUNSUMIO VELO?

LUNSUMIO VELO can cause Cytokine Release Syndrome (CRS), a serious side effect that is common during treatment with LUNSUMIO VELO, and can also be severe or life-threatening.

Get medical help right away if you develop any signs or symptoms of CRS at any time, including:

- fever of 100.4°F (38°C) or higher
- chills
- low blood pressure
- fast or irregular heartbeat
- tiredness or weakness
- difficulty breathing
- headache
- confusion
- feeling anxious
- dizziness or light-headedness
- nausea
- vomiting

Due to the risk of CRS, you will receive LUNSUMIO VELO on a "step-up dosing schedule".

- The step-up dosing schedule is when you receive smaller "step-up" doses before receiving higher doses of LUNSUMIO VELO during your first cycle of treatment.
- If your dose of LUNSUMIO VELO is delayed for any reason, you may need to repeat the "step-up dosing schedule."
- You may receive medicines to help reduce your risk of CRS before your dose.
- See **"How will I receive LUNSUMIO VELO?"** for more information about how you will receive LUNSUMIO VELO.

Your healthcare provider will check you for CRS during treatment with LUNSUMIO VELO and may treat you in a hospital if you develop signs and symptoms of CRS. Your healthcare provider may temporarily stop or completely stop your treatment with LUNSUMIO VELO if you have severe side effects.

See **"What are the possible side effects of LUNSUMIO VELO?"** for more information about side effects.

What is LUNSUMIO VELO?

LUNSUMIO VELO is a prescription medicine used to treat adults with follicular lymphoma whose cancer has come back or did not respond to previous treatment, and who have already received two or more treatments.

It is not known if LUNSUMIO VELO is safe and effective in children.

Before receiving LUNSUMIO VELO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or have had an infection in the past which lasted a long time or keeps coming back.
- have or had Epstein-Barr Virus.
- are pregnant or plan to become pregnant. LUNSUMIO VELO may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LUNSUMIO VELO.

  Females who are able to become pregnant:
  - your healthcare provider should do a pregnancy test before you start treatment with LUNSUMIO VELO.
  - use an effective method of birth control (contraception) during your treatment and for 3 months after the last dose of LUNSUMIO VELO.
- are breastfeeding or plan to breastfeed. It is not known if LUNSUMIO VELO passes into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of LUNSUMIO VELO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive LUNSUMIO VELO?

- LUNSUMIO VELO will be given to you by your healthcare provider as an injection under your skin (subcutaneous) in your stomach area (abdomen) or thigh.
- After you complete the weekly "step-up dosing schedule" in Cycle 1, LUNSUMIO VELO is given every 21 days.
- After Cycle 1, your healthcare provider will decide if you need to continue to take other medicines to help reduce side effects from LUNSUMIO VELO during future cycles.
- Your healthcare provider will decide how many treatment cycles you will receive of LUNSUMIO VELO.

See **"What is the most important information I should know about LUNSUMIO VELO?"** for more information about how you will receive LUNSUMIO VELO.

What should I avoid while receiving LUNSUMIO VELO?

Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.

See **"What is the most important information I should know about LUNSUMIO VELO?"** and **"What are the possible side effects of LUNSUMIO VELO?"** for more information about signs and symptoms of CRS and neurologic problems.

What are the possible side effects of LUNSUMIO VELO?

LUNSUMIO VELO can cause serious side effects, including:

See **"What is the most important information I should know about LUNSUMIO VELO?"**

- **Neurologic problems.** LUNSUMIO VELO can cause serious and life-threatening neurologic problems. Your healthcare provider will check you for neurologic problems during treatment with LUNSUMIO VELO. Your healthcare provider may also refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems during or after treatment with LUNSUMIO VELO, including:
  - headache
  - numbness and tingling of the arms, legs, hands, or feet
  - dizziness
  - confusion and disorientation
  - difficulty paying attention or understanding things
  - forgetting things or forgetting who or where you are
  - trouble speaking, reading, or writing
  - sleepiness or trouble sleeping
  - tremors
  - loss of consciousness
  - seizures
  - muscle problems or muscle weakness
  - loss of balance or trouble walking
  - tiredness
- **Serious infections.** LUNSUMIO VELO can cause serious infections that may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with LUNSUMIO VELO, including:
  - fever of 100.4°F (38°C) or higher
  - cough
  - chest pain
  - tiredness
  - shortness of breath
  - painful rash
  - sore throat
  - pain during urination
  - feeling weak or generally unwell
- **Hemophagocytic lymphohistiocytosis (HLH).** LUNSUMIO VELO can cause overactivity of the immune system, a condition called hemophagocytic lymphohistiocytosis (HLH). HLH can be life-threatening and has led to death in people treated with LUNSUMIO VELO. Your healthcare provider will check you for HLH especially if your CRS lasts longer than expected. Signs and symptoms of HLH include:
  - fever
  - enlarged spleen
  - easy bruising
  - low blood cell counts
  - liver problems
- **Low blood cell counts.** Low blood cell counts are common during treatment with LUNSUMIO VELO and can also be serious or severe. Your healthcare provider will check your blood cell counts during treatment with LUNSUMIO VELO. LUNSUMIO VELO can cause the following low blood cell counts:
  - **low white blood cell counts (lymphopenia and neutropenia).** Low white blood cells can increase your risk for infection.
  - **low red blood cell counts (anemia).** Low red blood cells can cause tiredness and shortness of breath.
  - **low platelet counts (thrombocytopenia).** Low platelet counts can cause bruising or bleeding problems.

- **Growth in your tumor or worsening of tumor related problems (tumor flare).** LUNSUMIO VELO can cause serious or severe worsening of your tumor. Tell your healthcare provider if you develop any of these signs or symptoms of tumor flare during your treatment with LUNSUMIO VELO:
  - chest pain
  - cough
  - trouble breathing
  - tender or swollen lymph nodes
  - pain or swelling at the site of the tumor

Your healthcare provider may temporarily stop or permanently stop treatment with LUNSUMIO VELO if you develop severe side effects.

The most common side effects of LUNSUMIO VELO include:

- injection site reactions
- tiredness
- rash
- CRS
- COVID-19
- muscle and joint pain
- diarrhea

The most common severe abnormal blood test results with LUNSUMIO VELO include: decreased white blood cell counts and increased uric acid levels.

These are not all of the possible side effects of LUNSUMIO VELO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LUNSUMIO VELO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about LUNSUMIO VELO that is written for health professionals.

What are the ingredients in LUNSUMIO VELO?

Active ingredient: mosunetuzumab-axgb

Inactive ingredients: acetic acid, histidine, methionine, polysorbate 20, sucrose, and Water for Injection.

Manufactured by: **Genentech, Inc.,** A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No.: 1048

For more information, call 1-844-832-3687 or go to www.LUNSUMIO.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: Dec 2025