

# NOW APPROVED IN 3L+ FL

## Impressive patient responses from the first-in-class FL T-cell engaging bispecific antibody<sup>1</sup>

80% (n=72/90) of patients taking LUNSUMIO™ achieved ORR (95% CI: 70%, 88%). Granted accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

## LUNSUMIO can be administered outpatient<sup>1</sup>

Hospitalization may be needed to manage select AEs, should be considered for subsequent infusions following a Grade 2 CRS event, and is recommended for subsequent infusions following a Grade 3 CRS event.



*Actor portrayal.*

**Lunsumio**<sup>™</sup>  
mosunetuzumab-axgb  
injection for intravenous use 1 mg | 30 mg

### Indication

LUNSUMIO (mosunetuzumab-axgb) 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

### Important Safety Information

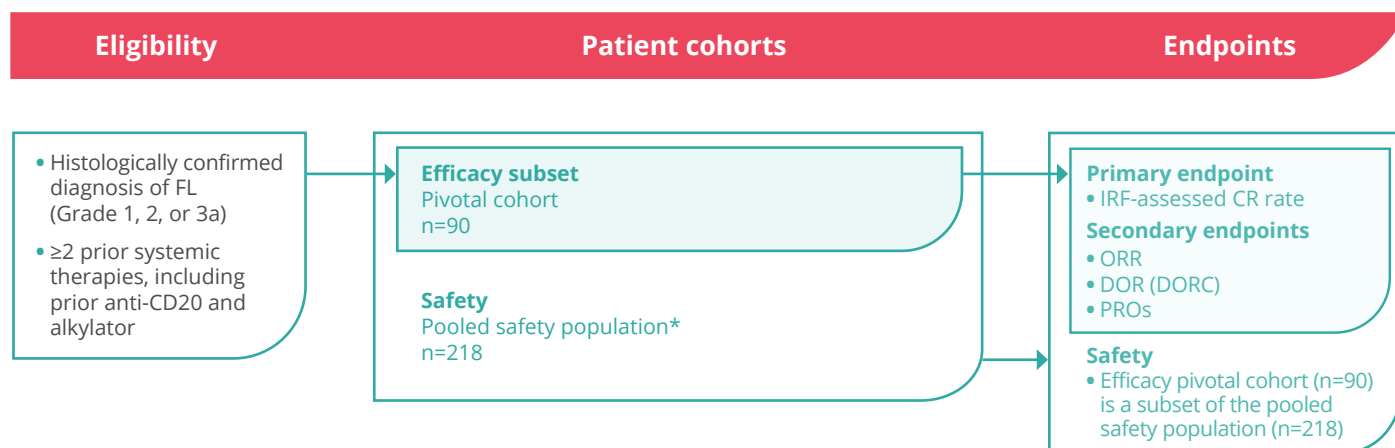
#### **BOXED WARNING**

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LUNSUMIO. 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.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

# FDA granted LUNSUMIO™ Breakthrough Therapy designation<sup>2</sup>

An open-label, multicenter, multi-cohort Phase II study (GO29781) evaluated LUNSUMIO in patients with 3L+ relapsed/refractory FL<sup>1,3</sup>



- Patients received step-up doses of LUNSUMIO intravenously as follows: 1 mg on Day 1 of Cycle 1, 2 mg on Day 8 of Cycle 1, 60 mg on Day 15 of Cycle 1, 60 mg on Day 1 of Cycle 2, and 30 mg on Day 1 of Cycle 3<sup>1</sup>
- 8 total cycles (~6 months) if CR was achieved, unless patients experienced progressive disease or unacceptable toxicity<sup>1</sup>
- 17 total cycles (~12 months) if PR/SD was achieved after 8 cycles, unless patients experienced progressive disease or unacceptable toxicity<sup>1</sup>
- 21 days/cycle<sup>1</sup>

\*Multi-cohort study in hematologic malignancies. LUNSUMIO is approved (accelerated approval) for R/R FL in patients who have received at least 2 prior therapies.

## Important Safety Information (cont'd)

### Warnings and Precautions

#### Cytokine Release Syndrome (CRS)

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

CRS occurred in 39% of patients who received LUNSUMIO at the recommended dose 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. Recurrent CRS occurred in 11% of patients. Most patients experienced CRS 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.

The median time to onset of CRS from the start of administration 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).

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

# Studied across a spectrum of high-risk patients (n=90)<sup>1,3</sup>

**77%**

Ann Arbor Stage  $\geq 3$

**52%**

POD24

**44%**

FLIPI  $\geq 3$

## Prior cancer treatment<sup>1,3</sup>

<b>Prior Cancer Therapy Regimen</b>	Prior Auto-SCT	<b>21%</b>
	Prior CAR-T	<b>3%</b>
	Prior PI3K	<b>19%</b>
	Prior Rituximab Plus Lenalidomide	<b>9%</b>
<b>Relapse/Refractory Status</b>	Refractory to Last Prior Therapy	<b>69%</b>
	Refractory to Any Prior Anti-CD20	<b>79%</b>
	Double Refractory to Prior Anti-CD20 and Alkylator	<b>53%</b>

## Other select patient characteristics<sup>1,3</sup>

**60 years**

Median Age  
(range: 29-90 years)

**100%**

ECOG PS 0-1

**34%**

Bulky Disease  
( $>6$  cm)

### Important Safety Information (cont'd)

#### Cytokine Release Syndrome (CRS) (cont'd)

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. 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.

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.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

**Lunsumio**<sup>™</sup>  
mosunetuzumab-axgb  
injection for intravenous use 1 mg | 30 mg

# Overall response seen in 8 out of 10 patients with durable remissions (n=90)<sup>1</sup>

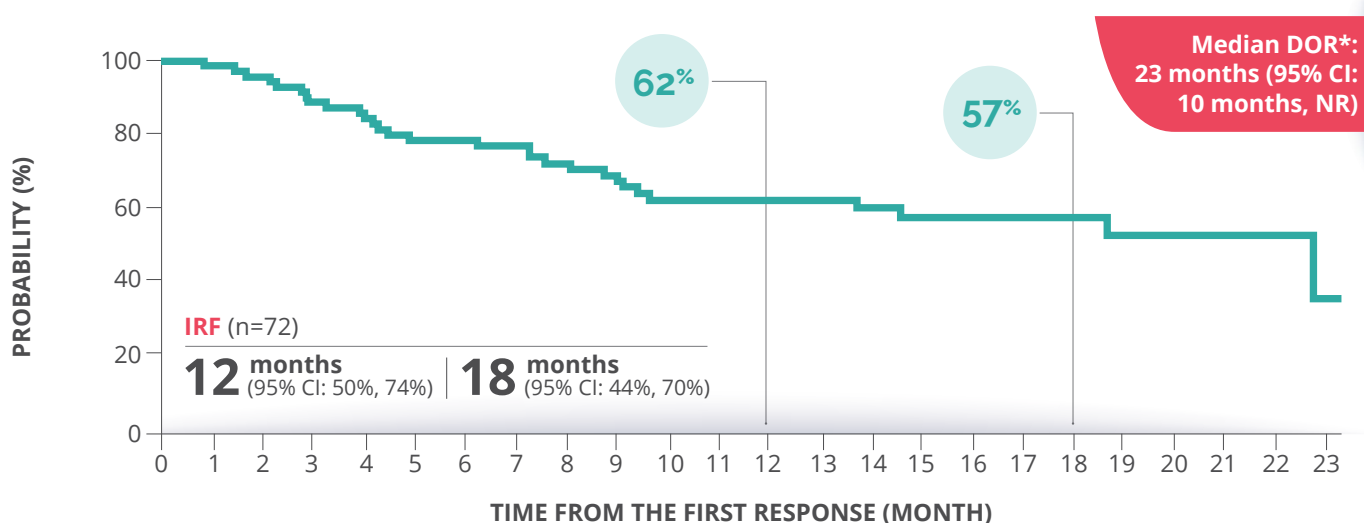


of patients achieved an overall response

(72/90 [95% CI: 70%, 88%])

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

A majority of patients maintained response at **18 months**<sup>3\*</sup>



Pts at risk	72	70	67	61	57	52	51	48	44	42	36	33	33	31	25	19	16	13	12	10	10	9	4	2
Pts censored	0	1	2	3	4	5	6	8	9	9	11	14	14	16	21	26	29	32	33	34	34	35	40	41

\*From the initial occurrence of the documented PR or CR.<sup>1</sup>

## Important Safety Information (cont'd)

### Neurologic Toxicity

LUNSUMIO can cause serious neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

Neurologic toxicity occurred in 39% of patients who received LUNSUMIO at the recommended dose 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 dose in the clinical trial.

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

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

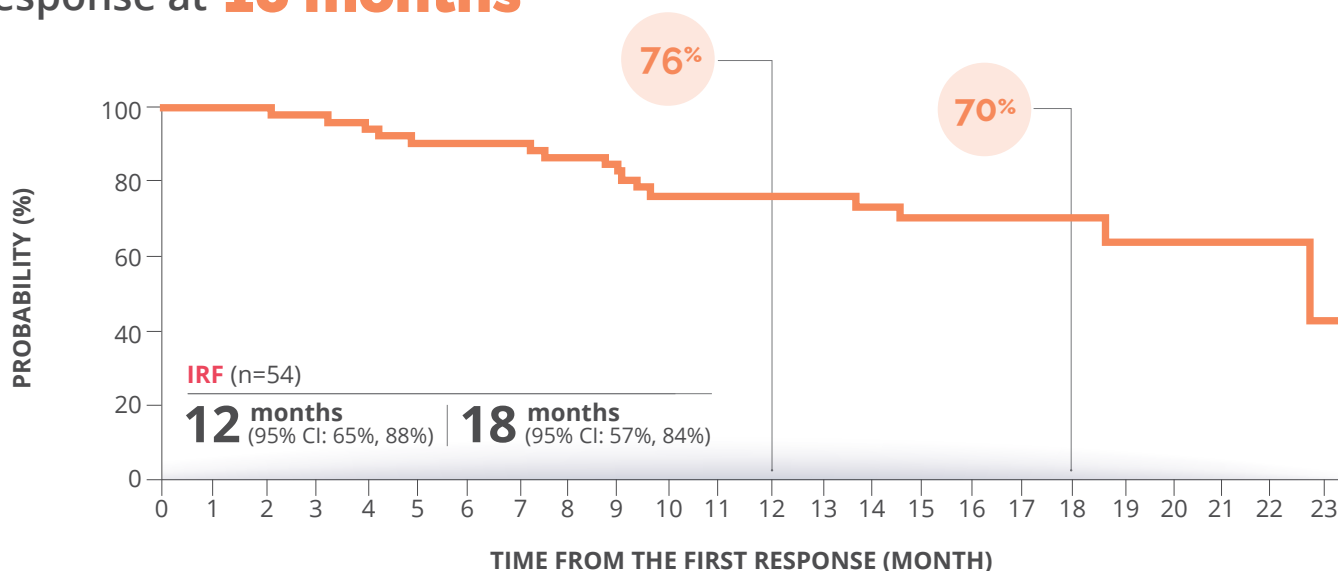
**Lunsumio**<sup>™</sup>  
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injection for intravenous use 1 mg | 30 mg

# Majority of patients achieved a **complete response** with LUNSUMIO™ (n=90)<sup>1</sup>



**of patients achieved a complete response**  
(54/90 [95% CI: 49%, 70%])

**7** out of **10** patients who achieved complete response maintained response at **18 months**<sup>3\*</sup>



	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
<b>Pts at risk</b>	54	54	53	52	50	48	48	46	43	42	36	33	33	31	25	19	16	13	12	10	10	9	4	2
<b>Pts censored</b>	0	0	1	1	1	1	1	3	4	4	6	9	9	11	16	21	24	27	28	29	29	30	35	36
<b>Pts with event</b>	0	0	0	1	3	5	5	5	7	8	12	12	12	12	13	14	14	14	14	15	15	15	15	16

\*From the initial occurrence of the documented PR or CR.<sup>1</sup>

## Important Safety Information (cont'd)

### Neurologic Toxicity (cont'd)

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.

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.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

# Exploratory analysis: response rates across subgroups with **high-risk** characteristics<sup>3</sup>

LUNSUMIO™ was studied across patient subgroups, including: age, refractory status, prior treatment, bulky disease, and FLIPI risk factors

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

Prior treatment type		
Demographic	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)

### Infections

LUNSUMIO can cause serious or fatal infections. Among patients who received LUNSUMIO at the recommended dose 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 tract infection.

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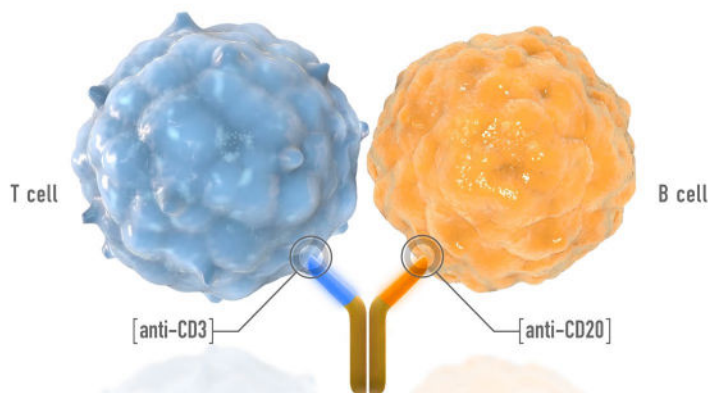


# The first approved bispecific antibody designed to target both CD20 on B cells and CD3 on T cells<sup>1</sup>

LUNSUMIO™ is a novel, first-in-class, T-cell engaging bispecific antibody in 3L+ FL<sup>1</sup>

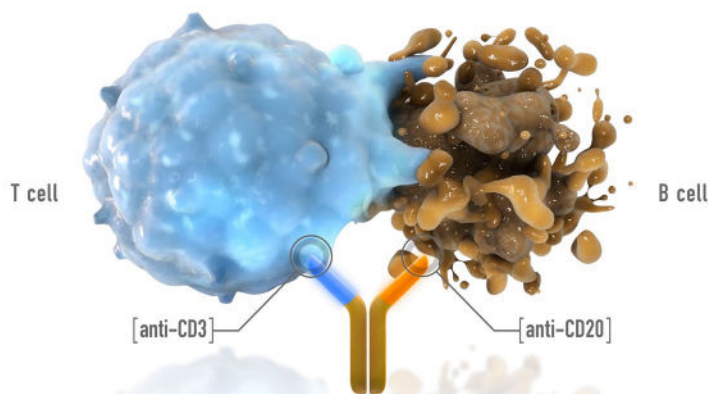
## Dual Targeting

LUNSUMIO binds to and links **CD20** on B cells and **CD3** on T cells.<sup>1</sup>



## Engage for Action

When both arms of LUNSUMIO are engaged, the T cell causes the release of proinflammatory cytokines and induces lysis of B cells.<sup>1</sup>



## Important Safety Information (cont'd)

### Infections (cont'd)

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.

### Cytopenias

LUNSUMIO can cause serious or severe cytopenias, including neutropenia, anemia, and thrombocytopenia. Among patients who received the recommended dosage in the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 38%, decreased hemoglobin in 19%, and decreased platelets in 12% of patients. Grade 4 decreased neutrophils occurred in 19% and decreased platelets in 5% of patients. Febrile neutropenia occurred in 2%.

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.

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**Lunsumio**<sup>™</sup>  
mosunetuzumab-axgb  
injection for intravenous use 1 mg | 30 mg

# Fixed treatment duration allows for a treatment-free period<sup>1</sup>



## Recommended dosing schedule (21-day treatment cycles):

Administer over a minimum of 4 hours

- 1 mg on Day 1 of Cycle 1
- 2 mg on Day 8 of Cycle 1
- 60 mg on Day 15 of Cycle 1

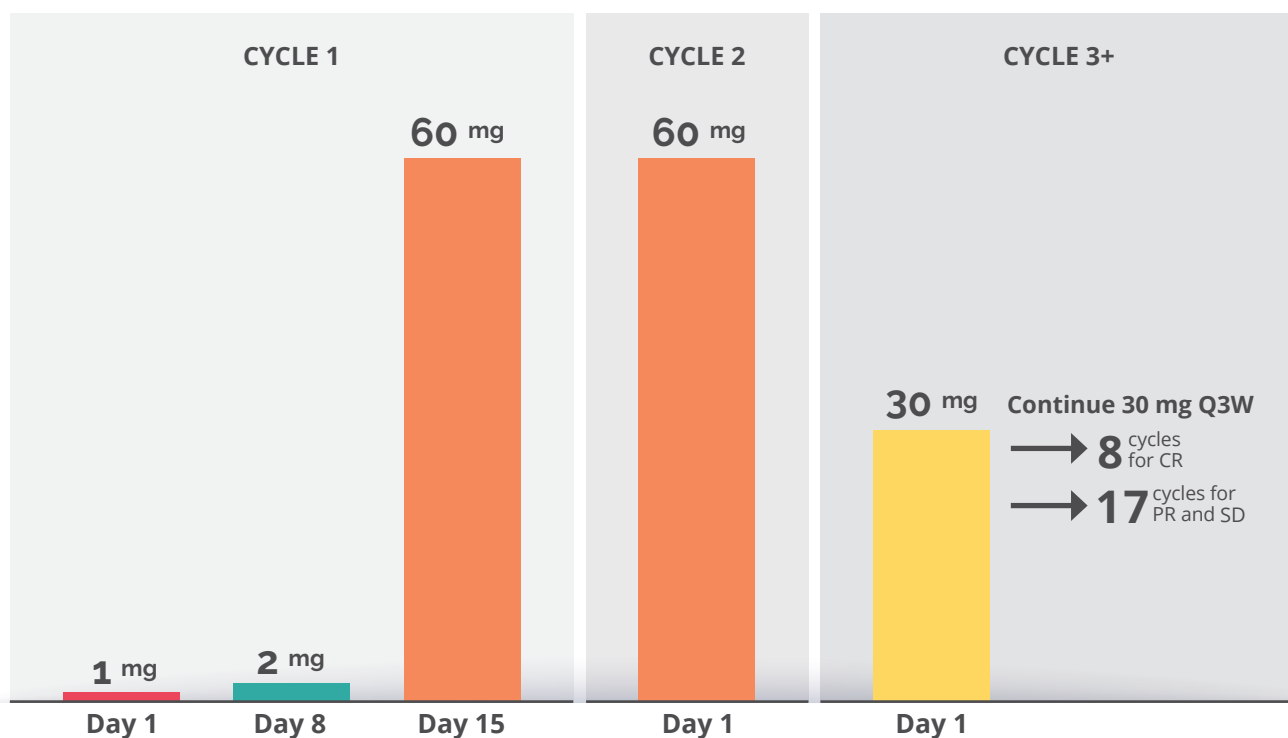
Administer over 2 hours if infusions from Cycle 1 were well-tolerated

- 60 mg on Day 1 of Cycle 2
- 30 mg on Day 1 of Cycle 3+



## Treatment duration depends on patient response:

- 8 cycles (~6 months) for patients who achieve a CR, unless there is disease progression or unacceptable toxicity
- 17 cycles (~12 months) for patients who achieve a PR or have SD after 8 cycles, unless there is disease progression or unacceptable toxicity



- Administer LUNSUMIO™ to well-hydrated patients
- Premedicate before each dose in Cycle 1 and Cycle 2
- 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

### Important Safety Information (cont'd)

#### Tumor Flare

LUNSUMIO 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% of patients.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.



# LUNSUMIO can be administered following a dose delay<sup>1</sup>

## Recommendations for restarting therapy with LUNSUMIO after dose delay

Last Dose Administered	Time Since the Last Dose Administered	Action for Next Dose(s)
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.
2 mg Cycle 1 Day 8	1 to 2 weeks	Administer 60 mg (Cycle 1 Day 15), then resume the planned treatment schedule.
	>2 weeks 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.
60 mg Cycle 1 Day 15	1 week 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.
60 mg Cycle 2 Day 1	3 weeks 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.
30 mg Cycle 3 onwards	3 weeks 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 Table 3 for all patients.

### Important Safety Information (cont'd)

#### Tumor Flare (cont'd)

Manifestations included new or worsening pleural effusions, localized pain and swelling at the sites of lymphoma lesions, and tumor inflammation.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

# LUNSUMIO™ safety profile<sup>1</sup>

## Adverse reactions (≥10%) in patients with relapsed or refractory FL who received LUNSUMIO (n=90)<sup>1</sup>

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

<sup>†</sup>Includes grouped terms as defined by the FDA. Definitions can be found in the LUNSUMIO Prescribing Information.

<sup>‡</sup>Only Grade 3 adverse reactions occurred.

### 3% of patients permanently discontinued LUNSUMIO due to ARs, including CRS and EBV viremia.<sup>1</sup>

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 cytokine release syndrome.<sup>1</sup>

### 2% rate of Grade 3 or 4 CRS was observed (n=90).<sup>1</sup>

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**Lunsumio**<sup>™</sup>  
mosunetuzumab-axgb  
injection for intravenous use 1 mg | 30 mg

# LUNSUMIO™ safety profile (cont'd)<sup>1</sup>

Select laboratory abnormalities (≥20%) that worsened from baseline in patients with relapsed or refractory FL who received LUNSUMIO<sup>1\*</sup>

Laboratory Abnormality	All Grades (%)	Grade 3 or 4 (%)
Lymphocyte count decreased	100	98
Hemoglobin decreased	68	12
White blood cells decreased	60	13
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.

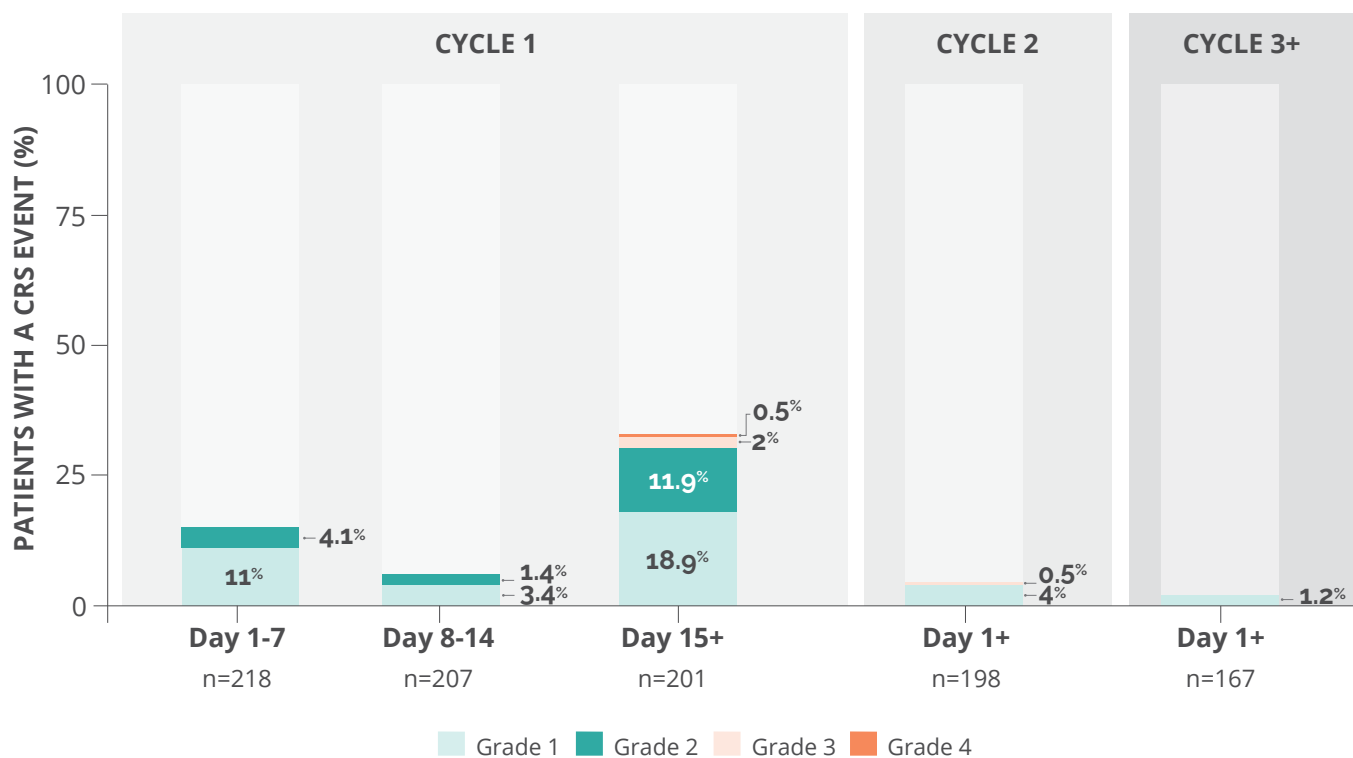
Clinically relevant adverse reactions in <10% of patients who received LUNSUMIO included pneumonia, sepsis, COVID-19, EBV viremia, mental status changes, tumor lysis syndrome, renal insufficiency, anxiety, motor dysfunction (including ataxia, gait disturbance, and tremor), and tumor flare.<sup>1</sup>

Serious adverse reactions occurred in 47% of patients who received LUNSUMIO. Serious adverse reactions in ≥2% of patients included cytokine release syndrome, infection (including urinary tract infection, sepsis, pneumonia, EBV viremia, and COVID-19), renal insufficiency, pyrexia, and tumor flare.<sup>1</sup>

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

# Observed CRS events with LUNSUMIO™ in the pooled safety population<sup>1,4\*</sup>

## Patients with CRS events by grade and cycle<sup>1,4</sup>



- CRS of any grade occurred in 39% (86/218) of patients<sup>1</sup>
- Grade 1 CRS occurred in 28% of patients, Grade 2 in 15%, Grade 3 in 2%, and Grade 4 in 0.5% of patients<sup>1</sup>
- Recurrent CRS occurred in 11% of patients<sup>1</sup>
- 93% of patients (80/86) with a CRS event were Grade 1-2<sup>4</sup>



**<1%** of patients discontinued treatment due to CRS. The median duration of CRS events was 3 days (range: 1-29 days)<sup>1,4</sup>

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

## Patients can receive LUNSUMIO™ outpatient<sup>1</sup>



LUNSUMIO can be administered in your local infusion center<sup>1</sup>



No hospitalization requirement at initiation of treatment<sup>1</sup>



Hospitalization may be needed to manage select AEs, should be considered for subsequent infusions following a Grade 2 CRS event, and is recommended for subsequent infusions following a Grade 3 CRS event<sup>1</sup>



Fixed treatment duration: In the pooled safety population, patients stayed on therapy a median of **8 cycles** (range: 1-17)<sup>1</sup>

### Important Safety Information (cont'd)

#### Tumor Flare (cont'd)

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.

#### 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. Verify pregnancy status in females of reproductive potential prior to initiating LUNSUMIO. Advise females of reproductive potential to use effective contraception during treatment with LUNSUMIO and for 3 months after the last dose.

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# We focus on access so you can focus on health

We work every day to help people who need our medicines, so they can focus on what matters most. People who take our medicines have several programs and resources available to them:



For people who need help understanding health insurance coverage and costs related to Genentech medicines:

## Genentech Access Solutions



For people who do not have health insurance coverage or who have concerns about the cost of their Genentech medicine and meet eligibility criteria:

## Genentech Patient Foundation\*



For people who have health insurance and can't afford their Genentech medicine:

## Affordability Options<sup>†</sup>



For people who want information and resources about a diagnosis and treatment with a Genentech medicine:

## Genentech Patient Education and Treatment Resources

\*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.

<sup>†</sup>Patients must meet eligibility criteria.



**Contact the Genentech Patient Resource Center for answers to your questions and to get your patients connected to the right Genentech patient support service. To learn more about our programs and services: visit [Genentech-Access.com](https://www.genentech-access.com) or call (877) GENENTECH**

3L=third-line; 3L+ FL=third-line or later follicular lymphoma; AE=adverse event; auto-SCT=autologous stem cell transplant; CAR=chimeric antigen receptor; CI=confidence interval; CR=complete response; CRS=cytokine release syndrome; DOR=duration of response; DORC=duration of response in patients who achieved CR; ECOG PS=Eastern Cooperative Oncology Group Performance Status; FL=follicular lymphoma; FLIPI=Follicular Lymphoma International Prognostic Index; IRF=independent review facility; NR=not reached; ORR=objective response rate; PI3K=phosphoinositide 3-kinase; POD24=progression of disease within 24 months from the start of initial therapy; PR=partial response; PROs=patient-reported outcomes; Pts=patients; Q3W=every 3 weeks; R/R=relapsed/refractory; SD=stable disease.

**References:** **1.** LUNSUMIO. Prescribing Information. Genentech, Inc. **2.** FDA grants Breakthrough Therapy Designation for Roche's CD20xCD3 bispecific cancer immunotherapy mosunetuzumab recognising its potential in follicular lymphoma. News release. Investor Update. July 14, 2020. Accessed December 17, 2021. <https://www.roche.com/investors/updates/inv-update-2020-07-14b.htm>. **3.** 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*. Published online July 5, 2022. doi:10.1016/S1470-2045(22)00335-7. **4.** Data on file. Genentech, Inc.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.



# Important Safety Information

## Important Safety Information (cont'd)

### Most Common Adverse Reactions

The most common ( $\geq 20\%$ ) adverse reactions were CRS (39%), fatigue (36%), rash (34%), pyrexia (24%), and headache (21%).

The most common Grade 3 to 4 laboratory abnormalities ( $\geq 10\%$ ) were decreased lymphocyte count (92%), decreased phosphate (41%), increased glucose (40%), decreased neutrophil count (38%), increased uric acid (15%), decreased white blood cell count (22%), decreased hemoglobin (19%), and decreased platelets (12%).

### Drug Interactions

LUNSUMIO 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 on Cycle 1 Day 1 and up to 14 days after the second 60 mg dose on Cycle 2 Day 1 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.

### 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 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](http://www.fda.gov/medwatch). You may also report side effects to Genentech at 1-888-835-2555.

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# LUNSUMIO™ IS NOW APPROVED IN 3L+ FL



First-in-class FL T-cell engaging bispecific antibody<sup>1</sup>



Impressive patient responses<sup>1</sup>

80% (n=72/90) of patients taking LUNSUMIO achieved ORR (95% CI: 70%, 88%). Granted accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).



Can be administered outpatient<sup>1</sup>

Hospitalization may be needed to manage select AEs, should be considered for subsequent infusions following a Grade 2 CRS event, and is recommended for subsequent infusions following a Grade 3 CRS event.

## Indication

LUNSUMIO (mosunetuzumab-axgb) 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. 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. 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.

Please see the LUNSUMIO full [Prescribing Information](#) for additional Important Safety Information, including **BOXED WARNING**.

Visit [LUNSUMIO-hcp.com](https://www.lunsumio-hcp.com) to learn more.

**Lunsumio**<sup>™</sup>  
mosunetuzumab-axgb  
injection for intravenous use 1 mg | 30 mg

**Genentech**  
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