

Lunsumio[™]

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

FACT SHEET

Media Inquiries:
(650) 467-6800

About Lunsumio

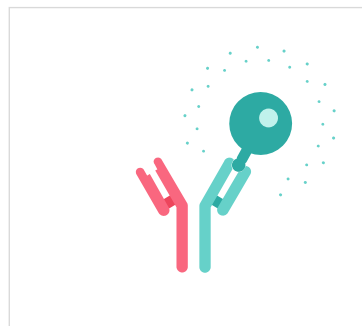
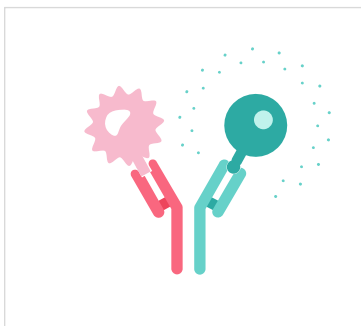
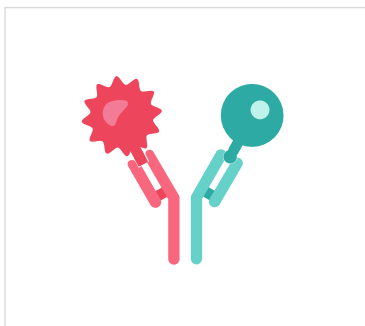
Lunsumio (mosunetuzumab-axgb) is a first-in-class CD20xCD3 T-cell engaging bispecific antibody approved by the U.S. Food and Drug Administration (FDA) for the treatment of **patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy**. The conditional approval of Lunsumio is based on response rate. There are ongoing studies to establish how well the drug works. Lunsumio is ready for infusion, allowing patients to start treatment immediately.

Building on a legacy of more than 20 years, Genentech scientists designed and developed Lunsumio as a type of cancer immunotherapy that provides patients with a chemotherapy-free treatment option.

FIRST CD20xCD3 T-CELL ENGAGING BISPECIFIC ANTIBODY APPROVED BY THE U.S. FDA

How Lunsumio is Designed to Work

Lunsumio is a CD20xCD3 T-cell engaging bispecific antibody designed with two arms that bind to two different targets on cells. One arm latches onto CD3, a protein on T cells, a type of immune cell, and the other latches onto CD20, a protein on B cells, which can be healthy or cancerous (malignant). Lunsumio brings the T cell within close proximity to the B cell, activating the release of cancer cell-killing proteins from the T cell.



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.

Please see additional Important Safety Information, including **Serious Side Effects**, in the LUNSUMIO full [Prescribing Information](#) and [Medication Guide](#).

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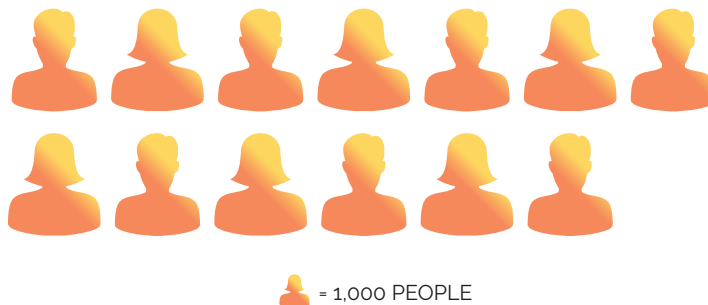
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About Follicular Lymphoma (FL)

FL is the most common slow-growing (indolent) form of non-Hodgkin's lymphoma (NHL).¹ In FL, a type of immune cell called B lymphocytes, or B cells, are affected. FL is most frequently diagnosed in people ages 65 to 74.² FL often returns after initial treatment.

~1 IN 5
CASES OF NHL ARE
FOLLICULAR LYMPHOMA

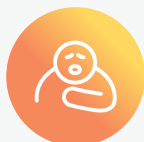
13K
ESTIMATED NEW CASES OF
FOLLICULAR LYMPHOMA IN
THE U.S. IN 2024



Common symptoms include:



**SWOLLEN, PAINLESS
LYMPH NODES**
in neck, armpits or groin



COUGHING
trouble breathing
or chest pain



ABDOMINAL PAIN
or feeling of fullness
in abdomen



**UNEXPLAINED
WEIGHT LOSS**



**SOAKING
NIGHT SWEATS**



**PERSISTENT
WEAKNESS AND
TIREDNESS**



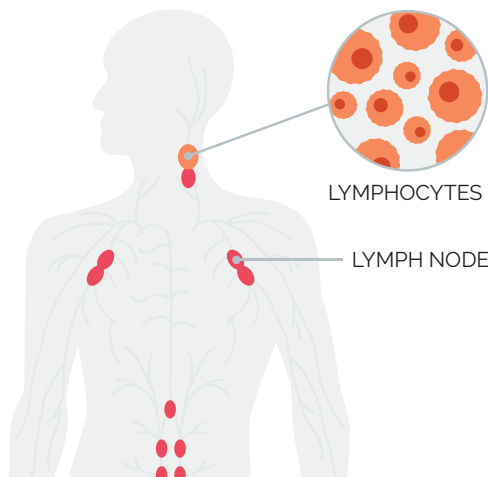
FEVER

Sometimes, patients with FL have no obvious symptoms of the disease at diagnosis.³

FL typically responds well to treatment but is often characterized by periods of remission and relapse. The disease typically becomes harder to treat each time relapse occurs. Patients whose disease progresses soon after initial treatment often have a poor long-term prognosis.

About Non-Hodgkin's Lymphoma

NHL is a disease in which malignant (cancerous) cells form in the lymph system, which is part of the immune system.⁴ NHL occurs when too many abnormal lymphocytes, a type of white blood cell, are produced.⁴ Normally, old lymphocytes die, and the body creates new ones to replace them. In people with NHL, these lymphocytes do not die but continue to grow and divide. This oversupply of lymphocytes crowds into lymph nodes, causing them to swell.⁴



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Lunsumio Efficacy and Safety⁵

The FDA approval of Lunsumio was based on positive results from a Phase II clinical trial in people with R/R FL who received two or more prior therapies. Results showed that 80% (ranging from 70-88%) of patients treated with Lunsumio achieved a response (overall response rate) with a median duration of response of 22.8 months (n=90). Treatment with Lunsumio helped 60% (ranging from 49-70%) of patients achieve complete remission (complete response). Among 218 patients with hematologic malignancies who received Lunsumio at the recommended dose, the most common side effect was CRS, which occurred in 39% of patients. CRS is a severe and life-threatening side effect of certain types of cancer immunotherapy that causes increased inflammation throughout the body, which can manifest as 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 or vomiting. Other common side effects (affecting 20% or more study participants) included tiredness, rash, fever and headache.

Lunsumio Dosing⁵

Lunsumio is administered as an intravenous (IV) infusion for a finite amount of time, which allows for time off therapy once the treatment course is completed. Because administration may be initiated outside of an academic center in the outpatient setting, Lunsumio may be accessible to patients and their healthcare providers across a wide variety of settings. Hospitalization may be needed to manage select adverse events, should be considered for subsequent infusion following a grade 2 CRS event, and is recommended for subsequent infusion following a grade 3 CRS event. Treatment duration depends on patient response. Patients who receive Lunsumio and achieve a complete response should receive eight cycles (each cycle lasting 21 days), unless there is disease progression or unacceptable toxicity. Patients who do not achieve complete remission after eight cycles should receive nine additional cycles (17 cycles total), unless there is disease progression or unacceptable toxicity. Prior to receiving Lunsumio, patients may receive a corticosteroid, an antihistamine and an antipyretic (fever-reducing medicine) to reduce the risk of CRS.

Important Safety Information

What is Lunsumio?

Lunsumio (mosunetuzumab-axgb) 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.

The conditional approval of Lunsumio is based on response rate. There are ongoing studies to establish how well the drug works.

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

Please see additional Important Safety Information, including **Serious Side Effects**, in the LUNSUMIO full [Prescribing Information](#) and [Medication Guide](#).

- 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

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.

What are the possible side effects of Lunsumio?

Lunsumio may cause serious side effects, including:

- **neurologic problems. Lunsumio can cause serious and life-threatening neurological 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 can be life-threatening and has led to death in people treated with Lunsumio. Your health care 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

Please see additional Important Safety Information, including **Serious Side Effects**, in the LUNSUMIO full [Prescribing Information](#) and [Medication Guide](#).

- **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: tiredness, rash, fever, and headache.

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

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 have 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 health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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.

These are not all the possible side effects of Lunsumio. Talk to your health care provider for more information about the benefits and risks of Lunsumio.

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

Please see Important Safety Information, including **Serious Side Effects**, as well as the Lunsumio full [Prescribing Information](#) and [Medication Guide](#).

1 American Cancer Society. Types of B-cell Lymphoma. <https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/about/b-cell-lymphoma.html>. Accessed January 7, 2025.

2 National Cancer Institute. SEER Cancer Stat Facts: NHL — Follicular Lymphoma. <https://seer.cancer.gov/statfacts/html/follicular.html>. Accessed January 7, 2025.

3 Lymphoma Research Foundation. Follicular Lymphoma. <https://www.lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/follicular-lymphoma/>. Accessed January 7, 2025.

4 American Cancer Society. What Is Non-Hodgkin Lymphoma? <https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html>. Accessed January 7, 2025.

5 Lunsumio (mosunetuzumab-axob) Prescribing Information. Genentech, Inc. 2024.

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