

European Commission approves Roche's first-in-class bispecific antibody Lunsumio for people with relapsed or refractory follicular lymphoma

- **Lunsumio® (mosunetuzumab) is the first CD20xCD3 T-cell engaging bispecific antibody available to treat the most common slow-growing form of non-Hodgkin lymphoma, follicular lymphoma (FL)**
- **Lunsumio represents a new type of immunotherapy that is a chemotherapy-free, off-the-shelf, fixed-duration treatment option that could improve outcomes for people who have relapsed or are refractory to multiple previous treatments**
- **Approval is based on the phase I/II GO29781 study, where Lunsumio induced high complete response rates, with the majority of complete responses lasting for at least 18 months in people with heavily pre-treated FL**

Basel, 8 June 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Commission has granted conditional marketing authorisation for the CD20xCD3 T-cell engaging bispecific antibody Lunsumio® (mosunetuzumab), for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least two prior systemic therapies. Lunsumio is an off-the-shelf therapy that is readily available, so people do not have to wait to start treatment.

Each year, more than 28,000 people in Europe are diagnosed with [FL](#), which accounts for approximately one in five non-Hodgkin lymphoma cases.^{1,2} Despite treatment advances, FL is considered an incurable disease and relapse is common, with outcomes worsening on each consecutive treatment.¹

“We are delighted that Lunsumio is the first bispecific antibody approved in Europe for people with relapsed or refractory follicular lymphoma,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “Lunsumio’s high response rates, off-the-shelf availability, and initial outpatient administration could transform how advanced follicular lymphoma is treated.”

“Having additional treatment options for people with follicular lymphoma, where multiple prior lines of therapy have failed, is critical to help them achieve better outcomes,” said Elizabeth Budde, M.D., Ph.D., Haematologic Oncologist and Associate Professor at City of Hope. “It is exciting to have a new class of immunotherapy like Lunsumio, offering a readily available, chemotherapy-free and fixed-duration treatment, with great potential to provide durable remissions without the need to stay on treatment continuously.”

The approval is based on positive results from the phase I/II GO29781 study where Lunsumio demonstrated high complete response rates, with the majority of complete responders maintaining responses for at least 18 months, and favourable tolerability in people with heavily pre-treated FL. After a median follow-up of 18.3 months, the median duration of response among responders was 22.8 months (95% CI: 9.7-not estimable), the complete response rate was 60% (n=54/90), the objective response rate was 80% (n=72/90). The most common adverse event was cytokine release syndrome (39%), which was generally low grade (grade 2: 14%), and resolved by the end of treatment. Other common ($\geq 20\%$) AEs were neutropenia, pyrexia, hypophosphatemia and headache. The initial dose was administered without mandatory hospitalisation. Results were presented for the first time in December 2021 at the 63rd American Society of Hematology Annual Meeting & Exposition.³

Conditional approval is granted to a medicinal product that fulfils an unmet medical need where the benefit of immediate availability outweighs the risk of less comprehensive data than normally required.

A robust development programme for Lunsumio is ongoing including two phase III studies: CELESTIMO, investigating Lunsumio plus lenalidomide in second line plus (2L+) FL, and SUNMO, investigating Lunsumio plus Polivy® (polatuzumab vedotin) in 2L+ diffuse large B-cell lymphoma (DLBCL).

This is Roche's second EU approval in lymphoma in 2022, following the approval of Polivy in combination with MabThera® (rituximab) plus cyclophosphamide, doxorubicin and prednisone (R-CHP) in previously untreated DLBCL.⁴ With a broad portfolio and pipeline, Roche is committed to providing treatment solutions for different stages of blood disorders, that are tailored to the disease, patient, physician, and healthcare system, as monotherapies or in combination with established and/or novel agents.

About Lunsumio® (mosunetuzumab)

Lunsumio is a first-in-class CD20xCD3 T-cell engaging bispecific antibody designed to target CD20 on the surface of B-cells and CD3 on the surface of T-cells. This dual targeting activates and redirects a patient's existing T-cells to engage and eliminate target B-cells by releasing cytotoxic proteins into the B-cells. A robust clinical development programme for Lunsumio is ongoing, investigating the molecule as a monotherapy and in combination with other medicines, for the treatment of people with B-cell non-Hodgkin lymphomas, including follicular lymphoma, diffuse large B-cell lymphoma, and other blood cancers.

About the GO29781 study

The GO29781 study [[NCT02500407](https://clinicaltrials.gov/ct2/show/study/NCT02500407)] is a phase I/II, multicentre, open-label, dose-escalation and expansion study evaluating the safety, efficacy and pharmacokinetics of Lunsumio® (mosunetuzumab) in people with relapsed or refractory B-cell non-Hodgkin lymphoma. Outcome measures include complete response rate (best response) by independent review

facility (primary endpoint), objective response rate, duration of response, progression-free survival, safety, and tolerability (secondary endpoints).

About follicular lymphoma

Follicular lymphoma (FL) is the most common indolent (slow-growing) form of non-Hodgkin lymphoma (NHL), accounting for about one in five cases of NHL.¹ It is considered incurable and relapse is common. It is estimated that more than 100,000 people are diagnosed with FL each year worldwide, including over 28,000 people in Europe.^{1,2}

About Roche in haematology

Roche has been developing medicines for people with malignant and non-malignant blood diseases for more than 20 years; our experience and knowledge in this therapeutic area runs deep. Today, we are investing more than ever in our effort to bring innovative treatment options to patients across a wide range of haematologic diseases. Our approved medicines include MabThera® (rituximab), Gazyvaro® (obinutuzumab), Polivy® (polatuzumab vedotin), Venclyxto® (venetoclax) in collaboration with AbbVie, and Hemlibra® (emicizumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies, glofitamab and Lunsumio® (mosunetuzumab), targeting both CD20 and CD3, and cevostamab, targeting both FcRH5 and CD3; Tecentriq® (atezolizumab), a monoclonal antibody designed to bind with PD-L1 and crovalimab, an anti-C5 antibody engineered to optimise complement inhibition. Our scientific expertise, combined with the breadth of our portfolio and pipeline, also provides a unique opportunity to develop combination regimens that aim to improve the lives of patients even further.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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References

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- [3] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/ Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥ 2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. Presented at: ASH Annual Meeting and Exposition; 2021 Dec 11-14. Abstract #127.
- [4] Roche's Polivy combination approved by European Commission for people with previously untreated diffuse large B-cell lymphoma [Internet; cited 2022 May]. Available from <https://www.roche.com/media/releases/med-cor-2022-05-25b>

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