Media & Investor Release

FDA approves Roche's Lunsumio VELO™ for subcutaneous use in relapsed or refractory follicular lymphoma

- **Lunsumio VELO reduces administration time from 2-4 hours to approximately one minute**
- **Availability of Lunsumio VELO allows treatment aligned to people's clinical needs and personal preferences**
- **Approval supported by data demonstrating compelling complete response rate in third-line or later follicular lymphoma, which typically becomes harder to treat after each relapse[1,2]**

Basel, 22 December 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved CD20xCD3 bispecific Lunsumio VELO™ (mosunetuzumab), as a subcutaneous (SC) formulation, for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy, based on results from the phase I/II GO29781 study.[1] Based on the study results, Lunsumio VELO is approved under accelerated approval. Full approval for this regimen may be contingent on verification and confirmation of benefit in a confirmatory trial.

"Since follicular lymphoma often requires lifelong management, reducing the burden of care for these individuals is of paramount importance," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "With this FDA approval, treatment can now be administered in just one minute, which significantly reduces the time patients spend in the clinic and helps to align care with their individual needs and preferences."

Lunsumio VELO reduces treatment administration time with an approximately one-minute injection, compared with a 2-4 hour intravenous (IV) infusion. Like Lunsumio administered intravenously, Lunsumio VELO can be administered outpatient and is a fixed-duration treatment given for a defined period, which could be as short as six months. By contrast, treat-to-progression treatment options are designed to be given to patients indefinitely until disease progression or until treatment can no longer be tolerated.

"This approval is a significant step in broadening access to effective treatments for people living with follicular lymphoma," said Dr Ian Flinn, MD, PhD, Tennessee Oncology and One Oncology. "With its manageable cytokine release syndrome profile and reduced administration time, Lunsumio VELO enables oncologists to deliver advanced care in community practice settings."

The FDA approval is supported by the primary analysis of the GO29781 study that evaluated Lunsumio VELO in patients with third-line or later (3L+) FL. Results showed the objective response rate and complete response rate in patients treated with Lunsumio VELO were 75% (95% confidence interval [CI]: 64–83%) and 59% (95% CI: 48–69%), respectively.[1] The median

duration of response was 22.4 months (95% CI: 16.8–22.8).[1] The most common adverse reactions (≥20%) were injection site reactions, fatigue, rash, cytokine release syndrome (CRS), COVID-19 infection, musculoskeletal pain and diarrhoea.[1] The CRS rate was 30% and events were mostly low grade (Grade 1–2, 28%; Grade 3, 2.1%), occurred during Cycle 1, and all resolved after a median duration of two days (range: 1–15).[1] CRS can be severe and life-threatening.

Lunsumio IV was the first bispecific antibody approved for 3L+ FL. Long-term data from the SC and IV arms of the GO29781 study were presented at the 67th American Society of Hematology Annual Meeting and Exposition.

These data have been submitted to other healthcare authorities around the world. Recently, the European Commission granted conditional marketing authorisation of Lunsumio SC for the treatment of adult patients with R/R FL after two or more lines of systemic therapy.

Roche continues to advance its bispecific antibody programme in lymphoma, with ongoing phase III studies evaluating Lunsumio and Lunsumio VELO in earlier lines of treatment. This includes the SUNMO study investigating Lunsumio VELO in combination with Polivy® (polatuzumab vedotin) in second-line or later large B-cell lymphoma, and the MorningLyte study investigating Lunsumio VELO in combination with lenalidomide in previously untreated FL.

About the GO29781 study

The GO29781 [NCT02500407] study is a phase I/II, multicentre, open-label, dose-escalation and expansion study evaluating the safety, efficacy and pharmacokinetics of mosunetuzumab administered both as an intravenous (IV) and subcutaneous (SC) treatment, in people with relapsed or refractory B-cell non-Hodgkin lymphoma. The efficacy of Lunsumio VELO™ (mosunetuzumab) was established on the basis of objective response rate and duration of response.

About follicular lymphoma

Follicular lymphoma (FL) is the most common slow-growing (indolent) form of non-Hodgkin lymphoma, accounting for about one in five cases.[3,4] It typically responds well to treatment but is often characterised by periods of remission and relapse.[3,4] The disease typically becomes harder to treat each time a patient relapses and early progression can be associated with poor long-term prognosis.[2] It is estimated that more than 110,000 people are diagnosed with FL each year worldwide.[4,5]

About Lunsumio VELO™ (mosunetuzumab)

Lunsumio VELO is a subcutaneous formulation of mosunetuzumab, a 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. Lunsumio VELO is being investigated as a monotherapy and in combination with other medicines, for the treatment of people with B cell non-Hodgkin lymphomas, including follicular lymphoma, large B-cell lymphoma, and other indications.

About Roche in haematology

Roche has been developing medicines for people with malignant and non-malignant blood diseases for more than 25 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®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), Polivy® (polatuzumab vedotin), Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, Hemlibra® (emicizumab), PiaSky® (crovalimab), Lunsumio® (mosunetuzumab administered intravenously), Lunsumio SC/VELO™ (mosunetuzumab administered subcutaneously) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes T-cell-engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3, and Tecentriq® (atezolizumab). 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.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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.

References

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