Media & Investor Release

CHMP recommends EU approval of Roche's subcutaneous formulation of Lunsumio for people with relapsed or refractory follicular lymphoma

- **Lunsumio provides high and long-lasting response rates, with approximately two-thirds of patients with a complete response in remission after four years[1]**
- **Subcutaneous Lunsumio has potential to substantially reduce treatment administration time with an approximately one minute injection, compared with 2-4 hours IV infusion**
- **If approved, Lunsumio would be the first treatment available for people with follicular lymphoma after two or more lines of systemic therapy, which is both fixed-duration and subcutaneously administered**

Basel, 19 September - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of a subcutaneous (SC) formulation of Lunsumio® (mosunetuzumab) for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy. A final decision is expected from the European Commission in the near future.

"Lunsumio was the first-ever approved CD20xCD3 T-cell engaging bispecific antibody demonstrating high, durable response rates and a favourable safety profile in third-line or later follicular lymphoma," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "If approved, the subcutaneous formulation could help to expand the treatment options available, offering people a fixed-duration therapy with a faster treatment administration time."

The CHMP opinion is based on results from a primary analysis of the phase II GO29781 study. Data show subcutaneous Lunsumio had pharmacokinetic non-inferiority compared to intravenous (IV) administration, with no unexpected safety signals. Overall, the rate and severity of cytokine release syndrome was low (29.8%); events were low grade (Grade 1-2, 27.7%; Grade 3, 2.1%), occurred during cycle 1 and all fully resolved in a median of two days (range 1-15 days).[2]

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Lunsumio administered subcutaneously has the potential to reduce the treatment administration time with an approximately one minute injection, compared with 2-4 hours for IV infusion, while retaining the same dosing schedule. Lunsumio is designed to be given for a fixed duration of approximately 6-12 months, depending on a patient's response to treatment, and can be initiated in the outpatient setting. This means people have a target end date for their course of treatment and the possibility of a treatment-free period.

Data from the phase II GO29781 study have been submitted to other health authorities around the world for approval consideration, including the US Food and Drug Administration.

Lunsumio, along with Columvi® (glofitamab), is part of Roche's industry-leading CD20xCD3 bispecific antibody portfolio. Continuing to explore new formulations and combinations of these medicines across different disease areas and lines of treatment is part of Roche's commitment to improve the patient experience and provide more choice, to suit diverse patient and healthcare system needs.

About the GO29781 study

The GO29781 study is a phase I/II, multicentre, open-label, dose-escalation and expansion study evaluating the safety, efficacy and pharmacokinetics of Lunsumio® (mosunetuzumab), administered both as an intravenous (IV) and subcutaneous (SC) treatment, in people with relapsed or refractory B-cell non-Hodgkin lymphoma. The primary objective for the SC cohort was to show pharmacokinetic (PK) non-inferiority of the SC formulation of Lunsumio compared to the IV formulation, based on the study's co-primary endpoints. Key secondary endpoints include complete response (CR) rate, objective response rate (ORR), duration of response, progression-free survival, safety and tolerability.

This recommendation is based on a primary analysis that explored Lunsumio administered subcutaneously in patients with third-line or later follicular lymphoma. Results showed PK non-inferiority compared to IV administration, and the ORR and CR rates in patients treated with the fixed-duration, subcutaneous formulation of Lunsumio were 74.5% (95% confidence interval (CI): 64.4% - 82.9%) and 58.5% (95% CI: 47.9% - 68.6%) respectively, as evaluated by the independent review facility. The median duration of CR was 20.8 months (95% CI: 18.8-not evaluable [NE]) for patients receiving Lunsumio via SC administration. The most common all-grade adverse events were injection-site reactions (60.6%; all Grade 1-2), fatigue (35.1%), and cytokine release syndrome (CRS; 29.8%). Overall, the rate and severity of CRS was low; events

were low grade (Grade 1-2, 27.7%; Grade 3, 2.1%), occurred during cycle 1 and all fully resolved in a median of two days (range 1-15 days).[2]

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] The disease typically becomes harder to treat each time a patient relapses, and early progression can be associated with poor long-term prognosis.[4] It is estimated that more than 110,000 people are diagnosed with FL each year worldwide.[4,6]

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 and diffuse large B-cell lymphoma, other blood cancers and autoimmune disorders.

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) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes T-cell-engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3, and off-the-shelf allogeneic CAR-T therapies. 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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