Media & Investor Release

FDA grants Priority Review to Roche's Lunsumio for people with relapsed or refractory follicular lymphoma

- **Lunsumio® (mosunetuzumab) could be the first CD20xCD3 T-cell engaging bispecific antibody approved by the FDA for the treatment of any type of non-Hodgkin lymphoma**
- **Application is based on results from the pivotal phase I/II study showing Lunsumio induced high and durable complete response rates in people with follicular lymphoma who received two or more prior therapies**
- **Lunsumio is a fixed-duration treatment option with the potential to be administered in an outpatient setting**

Basel, 6 July 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Biologics License Application (BLA) and granted Priority Review for Lunsumio® (mosunetuzumab), a potential first-in-class CD20xCD3 T-cell engaging bispecific antibody, for the treatment of adults with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least two prior systemic therapies. FL is the most common indolent (slow growing) form of non-Hodgkin lymphoma (NHL), a type of blood cancer, which often returns after initial therapy. The FDA is expected to make a decision on approval of this novel cancer immunotherapy by 29 December 2022.

"New therapeutic options are needed for follicular lymphoma, which often relapses after initial therapy and becomes increasingly difficult to treat each time it returns. Clinical trial results have demonstrated durable responses with Lunsumio in advanced follicular lymphoma, representing a step toward shifting the treatment paradigm," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Since Lunsumio does not require the collection or genetic modification of patient cells, it could become an effective, fixed-duration outpatient option without the barriers of travelling to a major academic centre."

The BLA is based on positive results from the pivotal phase I/II GO29781 study of Lunsumio, which showed high complete response (CR) rates, with the majority of responders (57% [95% CI: 49-70]) maintaining responses for at least 18 months, and manageable tolerability in people with heavily pretreated FL. After a median follow-up of 18.3 months, the CR rate was 60% (n=54/90) and the objective response rate was 80% (n=72/90). The median duration of response among those who responded was 22.8 months (95% CI: 9.7-not estimable). The most common adverse event (AE) was cytokine release syndrome (39%; n=86/218), which was generally low grade (grade 1: 25.6%; grade 2: 14%; grade 3: 2.3%; grade 4: 0.5%), and all events resolved. Other common AEs (>20%) included fatigue, headache, neutropaenia, fever and hypophosphataemia. Treatment was administered without mandatory hospitalisation.

Results were presented for the first time in December 2021 at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition.

Priority Review designation is granted to medicines that the FDA considers to have the potential to provide significant improvements in the safety and effectiveness of the treatment, prevention or diagnosis of a serious disease. The FDA granted Breakthrough Therapy designation (BTD) to Lunsumio for the treatment of adults with R/R FL who have received at least two prior systemic therapies in June 2020 and Orphan Drug Designation in December 2018. BTD is designed to accelerate the development and review of medicines intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate substantial improvement over existing therapies. The European Commission granted conditional marketing authorisation for Lunsumio for the treatment of people with R/R FL who have received at least two prior systemic therapies in June 2022.

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).

About the GO29781 study

The GO29781 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 slow-growing (indolent) form of non-Hodgkin lymphoma, accounting for about one in five cases. It typically responds well to treatment but is often characterised by periods of remission and relapse. The disease typically becomes harder to treat each time a patient relapses, and early progression can be associated with poor long-term prognosis. In the United States, it is estimated that approximately 13,000 new cases of FL will be diagnosed in 2022.

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 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.

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