Media & Investor Release

FDA approves Roche's Lunsumio, a first-in-class bispecific antibody, to treat people with relapsed or refractory follicular lymphoma

- **With Lunsumio, people with heavily pre-treated follicular lymphoma may experience remission with a chemotherapy-free, fixed-duration treatment that can be accessed in an outpatient setting**
- **Results from the pivotal phase II GO29781 study demonstrated that 80% of patients who received at least two prior therapies achieved durable response rates, with 60% experiencing complete remission**
- **Lunsumio is now the first CD20xCD3 T-cell engaging bispecific antibody approved by the FDA to treat the most common slow-growing form of non-Hodgkin lymphoma, follicular lymphoma**

Basel, 23 December 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Lunsumio® (mosunetuzumab-axgb) for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Lunsumio, a CD20xCD3 T-cell engaging bispecific antibody, represents a new class of fixed-duration cancer immunotherapy, which is off-the-shelf and readily available, so that patients do not have to wait to start treatment. Lunsumio will be available in the United States in the coming weeks.

"This approval is a significant milestone for people with relapsed or refractory follicular lymphoma, who have had limited treatment options until now," said Elizabeth Budde, M.D., Ph.D., Haematologic Oncologist and Associate Professor, City of Hope Division of Lymphoma, Department of Hematology & Hematopoietic Cell Transplantation, and Lunsumio clinical trial investigator. "As a first-in-class T-cell engaging bispecific antibody that can be initiated in an outpatient setting, Lunsumio's high response rates and fixed-duration could change the way advanced follicular lymphoma is treated."

"Despite treatment advances, follicular lymphoma remains incurable and relapse is common, with outcomes worsening following each consecutive treatment," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Lunsumio represents our first approved T-cell engaging bispecific antibody and builds on our legacy of more than 20 years of innovation in blood cancer."

The FDA approval is based on positive results from the phase II GO29781 study of Lunsumio in

people with heavily pre-treated FL, including those who were at high risk of disease progression or whose disease was refractory to prior therapies. Results from the study showed high and durable response rates. An objective response was seen in 80% (72/90 [95% confidence interval (CI): 70-88]) of patients treated with Lunsumio, with a majority maintaining responses for at least 18 months (57% [95% CI: 44-70]). The objective response rate is the combination of complete response (CR) rate (a disappearance of all signs and symptoms of cancer) and partial response rate (a decrease in the amount of cancer in the body). The median duration of response among those who responded was almost two years (22.8 months [95% CI: 10-not reached]). A CR was achieved in 60% of patients (54/90 [95% CI: 49-70]). Among 218 patients with haematologic malignancies who received Lunsumio at the recommended dose, the most common adverse event (AE) was cytokine release syndrome (CRS; 39%), which can be severe and life-threatening. The median duration of CRS events was three days (range: 1-29). Other common AEs (≥20%) included fatigue, rash, pyrexia and headache.

Lunsumio is administered as an intravenous infusion for a fixed-duration, which allows for time off therapy, and can be infused in an outpatient setting. Hospitalisation may be needed to manage select AEs, should be considered for subsequent infusions following a Grade 2 CRS event, and is recommended for subsequent infusions following a Grade 3 CRS event.

Lunsumio was developed based on the Roche Group's broad expertise in creating bispecific antibodies. Lunsumio is designed to address the diverse needs of people with blood cancer, physicians, and practice settings, and is part of the company's robust bispecific antibody clinical programme in lymphoma. Lunsumio is being further investigated as a subcutaneous formulation (i.e., administered under the skin) and in phase III studies that will expand the understanding of its impact in earlier lines of treatment in people with non-Hodgkin lymphoma.

About the GO29781 study

The GO29781 study [NCT02500407] is a phase II, multicentre, open-label, dose-escalation and expansion study evaluating the safety, efficacy and pharmacokinetics of Lunsumio® (mosunetuzumab-axgb) 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.[1] 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. It is estimated that, in the United States, approximately 13,000 new cases of FL will be diagnosed in 2022 and more than 100,000 people are diagnosed with FL each year worldwide.[1,2]

About Lunsumio® (mosunetuzumab-axgb)

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, 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®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), Polivy® (polatuzumab vedotin), Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, Hemlibra® (emicizumab) and Lunsumio® (mosunetuzumab-axgb). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies, glofitamab, 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 recognising our endeavour 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.

References

[1] Adult Non-Hodgkin Lymphoma Treatment-Health Professional Version (PDQ®) National Cancer Institute [Internet; cited 2022 December]. Available from https://www.cancer.gov/types/lymphoma/hp/adult-nhl-treatment-pdq#link/_552_toc.

[2] World Health Organization. GLOBOCAN 2020, Cancer Incidence and Mortality: IARC CancerBase No. 11 [Internet; cited 2022 December]. Available from: https://gco.iarc.fr/today/online-analysis-table?v=2020&mode=cancer&mode_population=continents&population=900&populations=908&key=asr&sex=0&cancer=39&type=0&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=17&group_cancer=1&include_nmsc=1&include_nmsc_other=#collapse-group-1-4-0.

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