Media & Investor Release

CHMP recommends EU conditional approval of Roche's potential first-in-class bispecific antibody mosunetuzumab for people with relapsed or refractory follicular lymphoma

- **If approved, mosunetuzumab would be the first CD20xCD3 T-cell engaging bispecific antibody available to treat follicular lymphoma (FL) offering a new, off-the-shelf, fixed-duration treatment option**
- **The recommendation is based on the GO29781 study where mosunetuzumab induced high complete response rates, with the majority of complete responses lasting for at least 18 months in people with heavily pretreated FL**

Basel, 22 April 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended approval under conditional marketing authorisation for 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. Based on this positive CHMP opinion, a final decision regarding the conditional approval of mosunetuzumab is expected from the European Commission in the near future. Follicular lymphoma is the second most common form of lymphoma globally, accounting for 20% of all non-Hodgkin lymphomas (NHL) diagnosed worldwide.[1]

"The majority of people with follicular lymphoma experience frequent relapses, and with each successive therapy the duration of remission and survival shortens," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's decision acknowledges the potential of mosunetuzumab as an efficacious, readily available, fixed-duration option, and brings the possibility of new hope to people living with this disease."

More than 28,000 people in Europe are diagnosed with FL each year.[1,2] The majority of people with FL relapse within five years after initial treatment, and for those who have received two or more prior therapies, conventional treatment options are currently limited and are associated with low rates of complete and durable remissions.[3,4] If approved, mosunetuzumab will be a first-in-class CD20xCD3 T-cell engaging bispecific antibody in NHL.

The CHMP recommendation is based on positive results from the phase I/II GO29781 study where mosunetuzumab showed high complete response (CR) rates, with the majority of complete responders maintaining responses for at least 18 months, and favourable tolerability in people with heavily pretreated FL. After a median follow-up of 18.3 months, the CR rate was 60% (n=54/90), the objective response rate was 80% (n=72/90), and median progression-free survival was 17.9 months (95% CI: 10.1-not estimable). The median duration

of response among those who responded was 22.8 months (95% CI: 9.7-not estimable). The most common adverse event was cytokine release syndrome (44.4%) which was generally low grade (grade 1: 25.6%; grade 2: 16.7%), and resolved by end of treatment. Treatment 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. [5]

In June 2020, mosunetuzumab was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration for the treatment of adult patients with FL who have received at least two prior systemic therapies. A robust development programme for mosunetuzumab is ongoing including two phase III studies: CELESTIMO investigating mosunetuzumab plus lenalidomide in second line plus (2L+) FL, and SUNMO, investigating mosunetuzumab plus Polivy® (polatuzumab vedotin) in 2L+ diffuse large B-cell lymphoma (DLBCL).

This recommendation is Roche's second CHMP positive opinion in NHL in 2022, following the positive opinion for Polivy in combination with MabThera® (rituximab) plus cyclophosphamide, doxorubicin and prednisone in previously untreated DLBCL.[6] With our broad portfolio and pipeline, we are 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 mosunetuzumab

Mosunetuzumab is an investigational 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 mosunetuzumab 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 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 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 over 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 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 recognising 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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