Media & Investor Release

New pivotal data demonstrate clinical benefit of Roche's glofitamab, a potential first-in-class bispecific antibody for people with aggressive lymphoma

- **Data to be presented for the first time at ASCO and EHA 2022 show glofitamab induces high and durable complete response rates in people with heavily pre-treated diffuse large B-cell lymphoma [1]**
- **Glofitamab has the potential to offer a readily available, fixed-duration CD20xCD3 bispecific antibody treatment approach for people with aggressive lymphoma**
- **Glofitamab is part of Roche's industry-leading CD20xCD3 bispecific antibody development programme, which aims to address the diverse needs and preferences of people with blood cancers**

Basel, 27 May 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new pivotal data on its investigational CD20xCD3 T-cell engaging bispecific antibody, glofitamab, will be presented for the first time at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting from 3-7 June and the European Hematology Association (EHA) 2022 Congress from 9-12 June. Data from the phase II NP30179 expansion study demonstrated that, after a median follow-up of more than 12 months, fixed-duration glofitamab (given for a fixed amount of time, and not taken until disease progression) induces durable complete responses (CRs) in patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who had received a median of three prior therapies.[1]

"These data bring us one step closer towards our goal of finding solutions for people with heavily pre-treated diffuse large B-cell lymphoma, which often relapses and becomes more aggressive each time it returns," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "The potential of glofitamab as a new fixed-duration, readily available treatment could be instrumental to improving outcomes for people with this difficult-to-treat cancer who otherwise have limited options."

The pivotal phase II NP30179 expansion study included patients with heavily pre-treated and highly refractory DLBCL, with 58.3% of patients refractory to their initial therapy and about one-third (33.1%) having received prior CAR T-cell therapy.[1] After a median follow-up of 12.6 months, 39.4% of patients (n=61/155) achieved a CR (primary efficacy endpoint) and half of them (51.6%; n=80/155) achieved an overall response (the percentage of patients with a partial or complete response; secondary efficacy endpoint), as assessed by an independent review committee. The majority (77.6%) of complete responses were durable and ongoing at 12 months and the median duration of complete response had not yet been reached (not

evaluable [16.8 months, not evaluable]). Cytokine release syndrome (CRS) was the most common adverse event occurring in 63.0% of patients. CRS events were predictable, generally low grade (mainly Grade 1 [47.4%] or 2 [11.7%]), occurred at initial doses, and only one patient discontinued glofitamab due to CRS. Incidence of Grade 3+ CRS was low (3.9%), with no Grade 5 events.[1]

"I'm encouraged by these data as they signify new hope for these patients who otherwise have limited effective treatment options and have faced disappointment from not responding to multiple rounds of treatments," said Associate Professor Michael Dickinson, Haematologist and Lead of the Aggressive Lymphoma Disease Group within Clinical Haematology at Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Australia. "These glofitamab data suggest that patients may be able to achieve durable responses with a set course of treatment that they don't have to take continuously until disease progression."

Data from the NP30179 study have been submitted for approval to the European Medicines Agency (EMA), and submissions to additional health authorities worldwide, including to the U.S. Food and Drug Administration (FDA), are planned this year. Glofitamab is being investigated in several clinical trials and explored in earlier lines of lymphoma treatment.

Roche is committed to improving standards of care to enhance the treatment experience and outcomes for people with blood cancers and the scientific data we are sharing at ASCO and EHA from our portfolio propels us further towards this goal. Roche is investigating its CD20xCD3 T-cell engaging bispecific antibodies glofitamab and mosunetuzumab further as subcutaneous formulations and in additional phase III studies that will expand the understanding of their impact in earlier lines of treatment, with the aim of providing people with different types of lymphomas with robust and durable treatment outcomes. Additionally, the European Commission (EC) recently granted approval of Polivy® (polatuzumab vedotin) in combination with MabThera® (rituximab) plus cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL), and the EMA's Committee for Medicinal Products for Human Use recommended mosunetuzumab for approval for patients with R/R follicular lymphoma, who have received at least two prior systemic therapies.

Follow Roche on Twitter via @Roche and keep up to date with ASCO 2022 news and updates by using the hashtag #ASCO22. For exclusive materials sharing insights into Roche's vision and strategy, and providing context behind the data being presented, visit Roche's Oncology Newsroom here.

About glofitamab

Glofitamab 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. Glofitamab is based

on a novel structural format called '2:1'. It is engineered to have two 'Fab' regions which bind to CD20, and one 'Fab' region which binds to CD3. 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 glofitamab 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 diffuse large B-cell lymphoma and mantle cell lymphoma, and other blood cancers.

About the NP30179 study

The NP30179 study [NCT03075696] is a phase I/II, multicentre, open-label, dose-escalation and expansion study evaluating the safety, efficacy and pharmacokinetics of glofitamab in people with relapsed or refractory diffuse large B-cell lymphoma. Outcome measures include complete response rate by independent review committee (primary endpoint), overall response rate, duration of response, progression-free survival, safety and tolerability (secondary endpoints).

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, 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 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.

For more information, please visit www.roche.com.

References

[1] Dickinson M, et al. Glofitamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and ≥ 2 prior therapies: Pivotal phase II expansion results. Presented at: ASCO Annual Meeting; 2022 Jun 3-7; Chicago, IL, USA and virtual. Abstract #7500.

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