

## Roche presents updated data on novel CD20xCD3 bispecific cancer immunotherapy glofitamab in people with heavily pre-treated non-Hodgkin lymphomas

- Results from the phase I NP30179 study show durable complete responses with glofitamab in patients with aggressive and indolent lymphomas after a median of three prior lines of therapy
- Data feature in oral presentation at the European Hematology Association 25<sup>th</sup> Annual Congress Virtual Edition

Basel, 12 June 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced updated data on one of its investigational CD20xCD3 T-cell engaging bispecific antibodies, glofitamab (formerly known as CD20-TCB), in people with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL). Updated results from the phase I dose-escalation NP30179 study [[NCT03075696](#)] of glofitamab, administered via intravenous infusion for a fixed-duration of up to 12 21-day cycles, showed durable complete responses (CRs) in heavily pre-treated patients who had received a median of three prior lines of therapy. These data feature in an oral presentation (abstract #S241) at the European Hematology Association 25<sup>th</sup> Annual Congress Virtual Edition, taking place from 11-14 June 2020.

“Non-Hodgkin lymphomas such as diffuse large B-cell lymphoma may present considerable treatment challenges, especially cases involving multiple relapses,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We’re encouraged by these early results which support the potential of glofitamab for patients who have failed multiple prior lines of therapy and need new treatment options urgently.”

Updated efficacy data from the  $\geq 0.6$ mg and  $\geq 10$ mg cohorts showed high response rates across NHL subtypes.

- In the  $\geq 0.6$ mg cohorts, the investigator-assessed CR rate was 30.9% (38/123) for patients with aggressive NHL and the investigator-assessed overall response rate (ORR) was 45.5% (56/123). For patients with indolent NHL, the investigator-assessed CR rate was 52.2% (12/23) and the investigator-assessed ORR was 65.2% (15/23).
- In the  $\geq 10$ mg cohorts, the investigator-assessed CR rate was 34.1% (29/85) for patients with aggressive NHL and the investigator-assessed ORR was 49.4% (42/85). For patients with indolent NHL, the investigator-assessed CR rate was 50.0% (9/18) and the investigator-assessed ORR was 66.7% (12/18).
- CRs also appeared durable. Of the patients achieving a CR in the  $\geq 0.6$ mg cohorts, 72.7% (24/33) with aggressive NHL and 81.8% (9/11) with indolent NHL maintained their CR by the data cut-off date (17 April 2020). Median duration of CR was not reached in either group after a median follow-up of 10.2 months.

The safety profile of glofitamab was consistent with its mechanism of action. Common adverse events (AEs) occurring in over 15% of participants in the  $\geq 0.6$ mg cohorts (n=156) were cytokine release syndrome (CRS; n=88, 56.4%), neutropenia (n=48, 30.8%), pyrexia (n=47, 30.1%), anaemia (n=35, 22.4%) and thrombocytopenia (n=26, 16.7%). The majority of CRS events were low grade (Grade 1-2), were associated with the first cycle, and were manageable.

A robust clinical development programme for glofitamab is ongoing, investigating the molecule alone and in combination with other Roche and non-Roche molecules. Combination regimens include studies with Polivy® (polatuzumab vedotin), Tecentriq® (atezolizumab), MabThera®/Rituxan® (rituximab) and Gazyva®/Gazyvaro® (obinutuzumab) in NHL and other blood cancers, across a variety of settings and tumour types, including earlier treatment lines, to identify where glofitamab may be able to provide benefit over current treatment options.

### **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. 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.

Glofitamab is based on a novel structural format which we call '2:1', which refers to the structure of the antibody. It is engineered to have two 'Fab' regions which bind to CD20, and one 'Fab' region which binds to CD3. 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 CD20-positive B-cell non-Hodgkin lymphomas, including diffuse large B-cell lymphoma and follicular lymphoma, and other blood cancers.

### **About the NP30179 study**

The NP30179 study [[NCT03075696](https://clinicaltrials.gov/ct2/show/study/NCT03075696)] is a phase I/Ib, multicentre, open-label, dose-escalation study, evaluating the efficacy, safety, tolerability and pharmacokinetics of glofitamab. In this study, glofitamab is assessed as a single agent and in combination with Gazyva®/Gazyvaro® (obinutuzumab), following pre-treatment with a one-time, fixed dose of Gazyva/Gazyvaro, in people with relapsed or refractory B-cell non-Hodgkin lymphoma. Outcome measures include overall response rate, complete response rate per Lugano 2014 criteria, maximum tolerated dose, and tolerability.

### **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®/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 idasanutlin, a small molecule which inhibits the interaction of MDM2 with p53; T-cell engaging bispecific antibodies, glofitamab and mosunetuzumab, targeting both CD20 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**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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](http://www.roche.com).

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