Media & Investor Release

[Ad hoc announcement pursuant to Art. 53 LR] Roche's Columvi meets primary endpoint of overall survival in people with relapsed or refractory diffuse large B-cell lymphoma in Phase III STARGLO study

- **Columvi, in combination with chemotherapy, demonstrated a statistically significant improvement in overall survival for people with relapsed or refractory diffuse large B-cell lymphoma**
- **Data from the STARGLO study will be submitted to health authorities and presented at an upcoming medical meeting**

Basel, 15 April 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the Phase III STARGLO study met its primary endpoint of overall survival. The study demonstrated that people with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), who have received at least one prior line of therapy and are not candidates for autologous stem cell transplant, lived longer when treated with Columvi® (glofitamab) in combination with gemcitabine and oxaliplatin (GemOx) versus MabThera®/Rituxan® (rituximab) in combination with GemOx. Safety of the combination appeared consistent with the known safety profiles of the individual medicines. The data will be submitted to health authorities and shared at an upcoming medical meeting.

"People with this aggressive lymphoma facing relapse or progression after initial treatment have limited options – particularly those who are ineligible for stem cell transplant," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Building on Columvi's established benefits, these data demonstrate the potential of this combination regimen to improve survival outcomes in earlier lines of treatment."

Columvi was the first fixed-duration bispecific antibody to receive accelerated approval by the U.S. Food and Drug Administration and conditional marketing authorisation from the European Commission to treat people with R/R DLBCL after two or more lines of systemic therapy. These approvals were based on positive results of Columvi as a monotherapy from the pivotal Phase I/II NP30179 study in patients with R/R DLBCL who had previously received two or more prior treatments.

Columvi is a CD20xCD3 T-cell engaging bispecific antibody designed to be off-the-shelf and ready for infusion, so patients can start treatment soon after diagnosis. This is particularly important for patients with highly aggressive disease who are at risk of rapid disease progression. Columvi is given as a fixed-duration treatment, offering people with R/R DLBCL who have failed two or more lines of therapy a treatment end date and the possibility of a treatment-free period, unlike continuous treatments.

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About the STARGLO study

The STARGLO study [GO41944; NCT04408638] is a Phase III, multicentre, open-label, randomised study evaluating the efficacy and safety of Columvi® (glofitamab) in combination with gemcitabine plus oxaliplatin (GemOx) versus MabThera®/Rituxan® (rituximab) in combination with GemOx in patients with diffuse large B-cell lymphoma who have received at least one prior line of therapy and who are not candidates for autologous stem cell transplant.[1] Outcome measures include overall survival (primary endpoint), progression-free survival, complete response rate, objective response rate, duration of objective response (secondary endpoints), and safety and tolerability.[1]

About Columvi® (glofitamab)

Columvi is a CD20xCD3 T-cell engaging bispecific antibody designed to target CD3 on the surface of T-cells and CD20 on the surface of B-cells. Columvi was designed with a novel 2:1 structural format. This T-cell engaging bispecific antibody is engineered to have one region that binds to CD3, a protein on T-cells, a type of immune cell, and two regions that bind to CD20, a protein on B-cells, which can be healthy or malignant. This dual-targeting brings the T-cell in close proximity to the B-cell, activating the release of cancer cell-killing proteins from the T-cell. Columvi is part of Roche's broad and industry-leading CD20xCD3 T-cell-engaging bispecific antibody clinical development programme that also includes Lunsumio® (mosunetuzumab), which aims to provide tailored treatment options that suit the diverse needs, preferences, and experiences of people with blood cancers and healthcare systems. Roche is investigating Columvi as a monotherapy and in combination with other medicines, including Polivy® (polatuzumab vedotin), in earlier lines of treatment for people with B-cell non-Hodgkin lymphomas, including diffuse large B-cell lymphoma and other blood cancers.

About diffuse large B-cell lymphoma (DLBCL)

DLBCL is the most common form of non-Hodgkin lymphoma (NHL), accounting for about one in three cases of NHL.[2] DLBCL is an aggressive (fast-growing) type of NHL.[2] While it is generally responsive to treatment in the frontline, as many as 40% of people will relapse or have refractory disease, at which time salvage therapy options are limited and survival is short.[3] Improving treatments earlier in the course of the disease and providing much needed alternative options could help to improve long-term outcomes. Approximately 160,000 people worldwide are diagnosed with DLBCL each year.[2, 4]

About Roche in haematology

Roche has been developing medicines for people with malignant and non-malignant blood diseases for more than 25 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), Lunsumio® (mosunetuzumab) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3, Tecentriq® (atezolizumab), 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 fifteenth 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] ClinicalTrials.gov. A Phase III Study Evaluating Glofitamab in Combination With Gemcitabine + Oxaliplatin vs Rituximab in Combination With Gemcitabine + Oxaliplatin in Participants With Relapsed/Refractory Diffuse Large B-Cell Lymphoma: NCT04408638 [Internet; cited April 2024]. Available from: https://classic.clinicaltrials.gov/ct2/show/NCT04408638.
[2] UpToDate. Patient education: Diffuse large B cell lymphoma in adults (Beyond the Basics). [Internet; cited April 2024]. Available from: https://www.uptodate.com/contents/diffuse-large-b-cell-lymphoma-in-adults-beyond-the-basics.
[3] Sehn LH, et al. Diffuse Large B-Cell Lymphoma. N Engl J Med. 2021;384(9):842-858.
[4] World Health Organization. Numbers derived from GLOBOCAN 2022. Non-Hodgkin Lymphoma Factsheet [Internet; cited April 2024]. Available from: https://gco.iarc.who.int/media/globocan/factsheets/cancers/34-non-hodgkin-lymphoma-fact-sheet.pdf.

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