Media & Investor Release

New two-year follow-up of Roche's Columvi extends overall survival in relapsed or refractory diffuse large B-cell lymphoma patients

- **Updated data from the pivotal phase III STARGLO study continue to demonstrate a clinically meaningful improvement in overall survival with a 40% survival benefit for people with R/R DLBCL who are not candidates for transplant[1]**
- **89% of patients whose cancer had fully responded at the end of treatment with Columvi in combination with chemotherapy were still alive and 82% showed no signs of cancer one year post-treatment[1]**
- **Timely initiation of effective therapy at relapse or after initial therapy failure is critical for this aggressive, life-threatening disease**
- **Results demonstrate potential of the Columvi combination as a much-needed, off-the-shelf and fixed-duration treatment option**

Basel, 23 May 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today two-year follow-up data from the phase III STARGLO study. After a median follow-up of 24.7 months, data showed a 40% improvement in overall survival (OS) for patients treated with Columvi® (glofitamab) in combination with gemcitabine and oxaliplatin (GemOx) and OS was not reached, compared to 13.5 months for MabThera®/Rituxan® (rituximab) plus GemOx (R-GemOx).[1] These updated data continue to demonstrate the statistically significant and clinically meaningful survival benefit of this off-the-shelf, fixed-duration Columvi combination for 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 (ASCT).[1] Data will be presented in an oral session at the 61st American Society of Clinical Oncology (ASCO), 30 May – 3 June 2025.

"We are encouraged that the two-year follow-up data for Columvi reinforces its potential to extend the lives of many patients where prognosis has historically been poor," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "These findings demonstrate the potential lasting benefits of early and effective treatment initiation with a bispecific antibody for people with relapsed or refractory disease."

"When cancer comes back or doesn't respond to treatment, it's devastating for patients with DLBCL given the aggressive nature of the disease," said Haifaa Abdulhaq, MD, Professor, University of California San Francisco (UCSF), Director of Hematology, UCSF Fresno. "In my community practice, I've seen the potential of this Columvi combination to help patients start treatment quickly - providing lasting remissions and more time without ongoing therapy."

The benefit across key secondary endpoints, including progression-free survival (PFS) and complete remission (CR), was maintained for patients treated with the Columvi combination.[1] There was a 59% reduction in the risk of disease progression or death (hazard ratio = 0.41,

95% confidence interval: 0.29–0.58) and more than twice as many patients sustained a CR (58.5% vs. 25.3%).[1] Among patients with a CR at the end of the treatment period, 89% were alive and 82% had maintained remission one year after treatment.[1] Safety of the combination remained unchanged from the previous analysis and was consistent with the known safety profiles of the individual medicines.[1,2] Patients received a higher median number of cycles of the Columvi combination (11 versus 4), due to disease progression in the R-GemOx arm.[1,2] A higher rate of adverse events (AEs) was observed with the Columvi regimen. One of the most common AEs was cytokine release syndrome, which was generally low grade.[1]

Given the wide adoption of global treatment guidelines in real-world clinical practice, there are no biological or clinical differences in DLBCL management worldwide.[3-6] While second-line therapies have advanced, DLBCL can progress rapidly and many people are not candidates for, cannot tolerate, or do not have access to latest therapies.[7,8] There is an urgent need for treatments that are rapidly available upon a diagnosis of relapse, that can manage the disease and improve long-term outcomes.

Based on the STARGLO data, this Columvi combination is approved in more than 30 countries for people with R/R DLBCL who are not candidates for ASCT, including countries throughout the EU. Columvi in combination with GemOx was added to the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as an NCCN category 1 preferred recommendation for the treatment of people with second-line DLBCL who are not intended to proceed to transplant.†[3] Columvi monotherapy has been approved for use in R/R DLBCL after two or more prior lines of therapy in more than 60 countries worldwide.

Columvi is part of Roche's industry-leading CD20xCD3 bispecific antibody programme. Together with the clinical development of off-the-shelf allogeneic CAR T-therapies, Roche aims to provide tailored treatment options that suit the diverse needs, preferences, and experiences of people with blood cancers and healthcare systems.

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 relapsed or refractory 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, or who have received two or more prior lines of therapy. Preclinical research indicated an increased antitumour effect when combining Columvi with GemOx over GemOx alone, so the STARGLO study was initiated to further explore the potential complementary effects of the treatment combination. 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.

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 for the treatment of diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma.

As part of Roche's efforts to elevate treatment standards in the earlier stages of DLBCL, where there is the best opportunity to improve long-term outcomes and prevent relapse, Columvi is also being investigated in combination with Polivy® (polatuzumab vedotin) and MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) in previously untreated DLBCL in the phase III SKYGLO study [GO44145; NCT06047080].

About diffuse large B-cell lymphoma (DLBCL)

DLBCL is an aggressive (fast-growing) type of non-Hodgkin lymphoma (NHL) and the most common form, accounting for about one in three cases of NHL.[9] Approximately 160,000 people worldwide are diagnosed with DLBCL each year, with comparable incidence rates across regions.[9,10] Medical practices, including pathological classification, diagnosis, staging, initial treatment and relapse management, are similarly approached worldwide.[3-6] 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.[7,11] Improving treatments earlier in the course of the disease and providing much needed alternative options could help to improve long-term outcomes.

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), PiaSky® (crovalimab), Lunsumio® (mosunetuzumab) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3 and Tecentriq® (atezolizumab). 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.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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References

[1] Abramson J, et al. Glofitamab plus gemcitabine and oxaliplatin (Glofit-GemOx) in patients (pts) with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): 2-year (yr) follow-up of STARGLO. Presented at: ASCO Annual Meeting; 2025 May 30 - Jun 3. Abstract #7015.
[2] Abramson J, et al. Glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab-GemOx for relapsed or refractory diffuse large B-cell lymphoma (STARGLO): a global phase 3, randomised, open-label trial. Lancet 2024; 404 (10466): 1940-1954.
[3] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.1.2025.
[4] Tilly H, et al. Diffuse large B-cell lymphoma (DLBCL): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2015;26:v116-25.
[5] Zhu J, et al. Union for China Lymphoma Investigators of Chinese Society of Clinical Oncology. Chinese Society of Clinical Oncology (CSCO) diagnosis and treatment guidelines for malignant lymphoma 2021 (English version). Chin J Cancer Res. 2021;30;33(3):289-301.
[6] Wight J, et al. Diffuse large B-cell lymphoma: a consensus practice statement from the Australasian Lymphoma Alliance. Intern Med J. 2022;52(9):1609-1623.
[7] Fabbri N, et al. Second-line treatment of diffuse large B-cell lymphoma: Evolution of options. Semin Hematol 2023; 60(5): 305–312.
[8] Westin J, et al. CAR T cells as a second-line therapy for large B-cell lymphoma: A paradigm shift? Blood. 2022;139(18):2737–2746.
[9] UpToDate. Patient education: Diffuse large B cell lymphoma in adults (Beyond the Basics). [Internet; cited May 2025]. Available from: https://www.uptodate.com/contents/diffuse-large-b-cell-lymphoma-in-adults-beyond-thebasics.
[10] World Health Organization. Numbers derived from GLOBOCAN 2022. Non-Hodgkin Lymphoma Factsheet [Internet; cited May 2025]. Available from: https://gco.iarc.who.int/media/globocan/factsheets/cancers/34-nonhodgkin-lymphoma-fact-sheet.pdf.
[11] Sehn LH, et al. Diffuse Large B-Cell Lymphoma. N Engl J Med. 2021;384(9):842-858.

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