Media & Investor Release

Roche provides update on FDA Advisory Committee meeting on Columvi combination for people with relapsed or refractory diffuse large B-cell lymphoma

- **Columvi is the first bispecific antibody to show a statistically significant and clinically meaningful 41% survival benefit in R/R DLBCL in the phase III STARGLO study[1,2]**
- **There is an urgent need for effective, immediately available therapies that are broadly accessible to people with transplant-ineligible R/R DLBCL**
- **This first-of-its-kind Columvi combination could provide a much-needed, off-the-shelf and fixed-duration treatment option for patients who face poor prognosis**
- **The clinical and disease characteristics of the overall population enrolled in this multiregional clinical trial are representative and applicable to US patients**

Basel, 20 May 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that a US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) discussed the supplemental Biologics License Application (sBLA) for Columvi® (glofitamab) in combination with gemcitabine and oxaliplatin (GemOx) for the treatment of people with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who are not candidates for autologous stem cell transplant (ASCT).

“Columvi in combination with GemOx demonstrated a 41% reduction in risk of death in a phase III, randomised, multiregional clinical trial, supporting its recent approval by the European Commission and inclusion in the US National Comprehensive Cancer Network treatment guidelines as a category 1 preferred regimen,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “We believe the STARGLO results are applicable to US patients, with the global study population closely mirroring the real-world clinical profile of DLBCL patients in the US, and we will continue working with the FDA on the regulatory path forward.”

Today’s discussion focussed on the applicability of the phase III STARGLO results to the US patient population, with Committee members citing that further data are needed. The STARGLO study was a multiregional clinical trial (MRCT) that enrolled 274 patients globally across 62 sites in 13 countries, including the US, Australia, and multiple European countries, with the majority of patients (52%) enrolling outside of Asia.

The clinical and disease characteristics of the overall population enrolled in this multiregional clinical trial are representative of US patients with this disease today. On that basis the STARGLO results are applicable to US patients. Based on extensive guidelines and

real-world clinical practice, there are no biological or clinical differences for DLBCL management worldwide.[5,6,7,8] There is a broad and robust clinical development programme of Columvi, indicating that region and/or race are not relevant determinants of outcomes to treatment.[1,9,10]

“Many of the patients with DLBCL who I see in my clinic are similar to the patients reflected in this study, making the glofitamab-GemOx regimen an important potential treatment option,” said Krish Patel, MD, Director of Lymphoma Research, Sarah Cannon Research Institute. “These patients need more effective, readily available treatment options and the compelling results from STARGLO deliver on this need.”

A statistically significant 41% reduction in the risk of death (hazard ratio [HR]=0.59, 95% confidence interval [CI]: 0.40–0.89, p=0.011) was observed in patients treated with Columvi in combination with GemOx versus MabThera®/Rituxan® (rituximab) plus GemOx (R-GemOx).[1,2] The Columvi combination also met its key secondary endpoints, with a 63% reduction in risk of disease worsening or death (progression-free survival, PFS) compared to R-GemOx (HR=0.37; 95% CI: 0.25–0.55, p<0.0001).[1,2] Median OS was 25.5 months for people treated with the Columvi combination, nearly double what was seen for people treated with R-GemOx at 12.9 months (HR=0.62, 95% CI: 0.43-0.88) in a follow-up analysis.[1,2] Safety of the combination 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 four), due to disease progression in the R-GemOx arm. A higher rate of adverse events (AEs) was observed with the Columvi regimen.[1,2] One of the most common AEs was cytokine release syndrome, which was generally low grade (Any Grade: 44.2%, Grade 1: 31.4%, Grade 2: 10.5%, Grade 3: 2.3%) and occurred primarily in Cycle 1.[1,2] Two-year follow-up data from STARGLO will be presented at the upcoming 61st American Society of Clinical Oncology (ASCO) Annual Meeting from 30 May - 3 June 2025.

For people with DLBCL who have relapsed or refractory disease, therapy options that can provide durable remissions are limited. In the US, approximately 75% of patients with R/R DLBCL are not candidates for, cannot tolerate, or do not have access to latest treatments.[4,5] New treatments that can be initiated in community practices, where the majority of patients are treated, and have the potential to provide rapid disease control with durable remissions, could meaningfully address the needs of patients with this aggressive and life-threatening form of lymphoma.

Based on the STARGLO data, this Columvi combination is approved in more than 30 countries, including the EU, for people with R/R DLBCL who are ineligible for ASCT. Columvi in combination with GemOx was recently 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.[†6] 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, including the US. STARGLO is intended as a confirmatory study to convert the accelerated approval of Columvi in the US to full approval.

The ODAC provides the FDA with independent opinions and review of safety and efficacy data from outside medical experts, though the recommendations are not binding. The FDA's evaluation of this Columvi combination for R/R DLBCL is ongoing and a decision on approval is expected by 20 July 2025.

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.[7] Approximately 160,000 people worldwide are diagnosed with DLBCL each year, with comparable incidence rates across regions.[8,9] Medical practices, including pathological classification, diagnosis, staging, initial treatment and relapse management, are similarly approached worldwide.[9-12] 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.[4,13] 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.

†NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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