Media & Investor Release

Roche's Columvi combination shows sustained survival benefit at three-year follow up of pivotal phase III STARGLO study

- **Overall survival was twice as long for people treated with Columvi in combination with GemOx versus MabThera/Rituxan plus GemOx[1]**
- **This Columvi combination is available off-the-shelf and could offer a potentially curative treatment option for people with R/R DLBCL who are not candidates for transplant**
- **Columvi in combination with GemOx has now been approved in more than 50 countries worldwide and recommended in international treatment guidelines[2-4]**

Basel, 8 December 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today three-year follow-up data from the pivotal phase III STARGLO study in 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). After a median follow-up of 35.1 months, overall survival (OS) remained twice as long for people treated with Columvi® (glofitamab) in combination with gemcitabine and oxaliplatin (GemOx) versus MabThera®/Rituxan® (rituximab) plus GemOx (R-GemOx) (25.5 months versus 12.5 months, respectively [hazard ratio (HR)=0.60, 95% confidence interval (CI): 0.43-0.8]).[1] Results were presented at the 67th American Society of Hematology Annual Meeting and Exposition, 6-9 December 2025 in Orlando, Florida, US.

Subgroup analyses showed consistent results across clinically relevant subgroups of prior line of therapy and age.[1] The greatest efficacy benefit was seen in people who had received one prior line of therapy (second line, 2L), with 54.6% still alive at 36 months follow-up.[1] For these patients, median OS was not reached with Columvi in combination with GemOx versus 14.4 months (HR=0.58; 95% CI: 0.38-0.89) in the R-GemOx arm.[1] Median progression-free survival (PFS) was 20.4 versus 5.5 months (HR=0.41; 95% CI: 0.25-0.65).[1] In patients with 2L DLBCL with early relapse (within 12 months), who are typically harder to treat, the complete response rate was 56.0% and the 36 month OS rate was 46.1%.[5]

"At three years, we see flattening of the overall survival curve, suggesting the possibility of cure for relapsed/refractory DLBCL patients treated with glofitamab-GemOx," said Jeremy Abramson, MD, Director, Jon and Jo Ann Hagler Center for Lymphoma at the Mass General Brigham Cancer Institute, US, and principal investigator of the STARGLO study. "These data continue to underscore the meaningful benefit of Glofitamab plus GemOx for patients after initial relapse, when fast and effective treatment is critical given the aggressive nature of this disease."

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"By prolonging survival, this Columvi combination could offer people with relapsed or refractory DLBCL long-term remission, and potential additional time to spend with their loved ones without signs of disease or the need for continuous therapy," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The potential of Columvi in combination with GemOx continues to be recognised globally, with approvals in more than 50 countries around the world and inclusion in multiple international treatment guidelines."

Data add to the growing body of evidence supporting the value that this Columvi-based combination can bring to people with 2L+ DLBCL who are not candidates for ASCT or who face barriers accessing other treatment options. As an off-the-shelf and fixed-duration therapy, Columvi plus GemOx can be readily available for infusion in any setting, meaning patients could avoid crucial delays in starting treatment and allowing the possibility of a treatment-free period.

The safety profile was unchanged with extended follow up; no new signals were identified, and safety of the combination was consistent with the known safety profiles of the individual medicines. Cytokine release syndrome (CRS) remained the most common adverse event in people treated with Columvi plus GemOx (44.8%; Grade 1: 32.0%, Grade 2: 10.5%, Grade 3: 2.3%).[1] Immune recovery in the form of median B-cell and immunoglobulin M count was observed 18-24 months after end-of-treatment.[1]

Based on the STARGLO data, this Columvi combination is approved in more than 50 countries worldwide, including countries in the EU, the UK, Canada, Australia, China and Mexico, with additional submissions to health authorities ongoing*. Columvi in combination with GemOx is recommended in clinical practice guidelines including the European Society For Medical Oncology, European Hematology Association and the US National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with category 1 evidence for people with 2L+ DLBCL.†[2-4] The US Food and Drug Administration issued a Complete Response Letter for the supplemental Biologics License Application for Columvi in combination with GemOx for this indication.

Roche is continuing to explore the potential of Columvi across other settings including first-line (1L) DLBCL and mantle cell lymphoma (MCL) to elevate treatment standards even further. This includes the phase III SKYGLO study investigating Columvi in combination with Polivy® (polatuzumab vedotin), MabThera/Rituxan, cyclophosphamide, doxorubicin and prednisone, in 1L DLBCL, which has recently completed enrolment. In R/R MCL, the phase III GLOBRYTE study evaluating Columvi as a single agent versus investigator's choice of therapy is currently recruiting.

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 and mantle cell lymphoma.

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.[6] Approximately 160,000 people worldwide are diagnosed with DLBCL each year, with comparable incidence rates across regions.[7,8] Medical practices, including pathological classification, diagnosis, staging, initial treatment and relapse management, are similarly approached worldwide.[8-11] 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.[12,13] 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 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.

*Countries that have approved Columvi in combination with GemOx in R/R DLBCL include: Argentina, Australia, Bahrain, Bosnia and Herzegovina, Canada, China, the European Union, Iceland, Lebanon, Liechtenstein, Macedonia, Malaysia, Mexico, New Zealand, Norway, Oman, Paraguay, Peru, Qatar, South Korea, Taiwan, Thailand, United Arab Emirates, United Kingdom, Uruguay.

†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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