Media & Investor Release

CHMP recommends EU approval of Roche's Columvi combination for people with relapsed or refractory diffuse large B-cell lymphoma

- **Columvi plus chemotherapy showed a 41% reduction in the risk of death in the pivotal phase III STARGLO study[1,2]**
- **DLBCL—an aggressive disease with a high risk of progression—remains an area of high unmet need, especially for treatments that can be initiated soon after the cancer returns**
- **If approved, this off-the-shelf, fixed-duration Columvi combination will be the first bispecific antibody regimen available for patients with DLBCL following relapse**

Basel, 28 February 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Columvi® (glofitamab) in combination with gemcitabine and oxaliplatin (GemOx) for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) not otherwise specified who are ineligible for autologous stem cell transplant (ASCT). The standard second-line (2L) therapy for R/R DLBCL patients has historically been high-dose chemotherapy followed by stem cell transplant. New therapies have been recently introduced, however, not all patients can access or are eligible for these treatments.[3] If approved, this Columvi combination could provide a much-needed, off-the-shelf treatment option. A final decision is expected from the European Commission in the near future.

DLBCL is an aggressive (fast-growing) type of lymphoma and is one of the most prevalent types of blood cancer among adults. Each year in Europe, an estimated 38,000 people are diagnosed with DLBCL.[4,5] Approximately four out of ten patients will relapse after first line treatment and the majority of patients who require subsequent lines of therapy have poor outcomes.[6,7]

"For patients with DLBCL who relapse after initial therapy, urgent and effective treatment is required to regain disease control," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "As the first bispecific antibody to show improved survival in DLBCL in a randomised phase III study, Columvi could offer an additional treatment option that is immediately available for patients who relapse."

Whilst 2L treatment advances have been made, challenges with the accessibility of existing medicines and the aggressive nature of DLBCL underscores the urgent need for immediately available treatment options that can control the disease and improve survival.[3] Columvi is designed to be off-the-shelf and readily available for infusion, meaning patients can avoid crucial delays in starting their next treatment.

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The CHMP recommendation is based on results from the phase III STARGLO study, which were presented at the 29th European Hematology Association Congress and published in *The Lancet*.[1,2] Data showed Columvi in combination with GemOx demonstrated a statistically significant and clinically meaningful overall survival improvement versus MabThera®/Rituxan® (rituximab) and GemOx, with a 41% reduction in the risk of death.[1,2] Safety of the combination appeared consistent with the known safety profiles of the individual medicines.[1,2]

Columvi was the first fixed-duration bispecific antibody to receive conditional marketing authorisation in the EU as a monotherapy to treat people with R/R DLBCL after two or more lines of systemic therapy based on the pivotal phase I/II NP30179 study [NCT03075696]. STARGLO was intended as a confirmatory study for the conditional marketing authorisation of Columvi in the EU.

Columvi, along with Lunsumio® (mosunetuzumab), is part of Roche's industry-leading CD20xCD3 bispecific antibody portfolio, with more than 7,300 patients treated with these therapies to date.[8]

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, cyclophosphamide, doxorubicin and prednisone (R-CHP) in previously untreated DLBCL in the phase III SKYGLO study.

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 (R-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 (OS; primary endpoint), progression-free survival, complete response rate, objective response rate, duration of objective response (secondary endpoints), and safety and tolerability.

In the primary analysis (conducted after a median follow-up of 11.3 months) patients treated with Columvi plus GemOx lived significantly longer, with a 41% reduction in the risk of death (hazard ratio [HR]=0.59, 95% CI: 0.40-0.89, p=0.011) versus R-GemOx.[1,2] Median OS was not reached with the Columvi regimen versus nine months for R-GemOx.[1,2] Safety of the combination appeared consistent with the known safety profiles of the individual medicines.[1,2] Adverse event (AE) rates were higher with the Columvi combination versus R-GemOx, noting

higher median number of cycles received with the Columvi combination (11 versus 4).[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]

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.[4] Approximately 160,000 people worldwide are diagnosed with DLBCL each year.[4,9] 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.[6,7] 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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