Investor Update

Roche provides update on supplemental Biologics License Application for Columvi combination for people with relapsed or refractory diffuse large B-cell lymphoma

Basel, 18 July 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for Roche's 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.

Based on the CRL, the STARGLO data do not provide sufficient evidence to support the proposed second-line DLBCL indication in the US patient population. STARGLO was also intended as a postmarketing confirmatory study to convert the accelerated approval of Columvi in third-line or later DLBCL in the US to full approval. Columvi remains under accelerated approval for people with 3L+ DLBCL. Discussions with the FDA are ongoing to confirm the phase III SKYGLO study investigating Columvi in combination with Polivy® (polatuzumab vedotin), MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone for patients with previously untreated large B-cell lymphoma as the new postmarketing requirement.

“While we are disappointed with this outcome, we remain confident in the data supporting the value of Columvi for US patients who have relapsed following initial treatment, and its key role as monotherapy in the third-line setting,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are committed to bringing Columvi to more people living with lymphoma and are actively exploring its potential in additional treatment settings, including as frontline therapy.”

"For patients with this aggressive form of lymphoma, effective treatment after relapse is paramount. The STARGLO study showed that Columvi-GemOx significantly improves overall survival and could have a positive impact for patients earlier in their treatment journey. This regimen is already approved in over 35 countries, which underscores the urgent need it addresses," said Jeremy Abramson, MD, Director, Jon and Jo Ann Hagler Center for

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland

Investor Relations
email:
investor.relations@roche.com

Tel. +41 61 68-88880
www.roche.com

Lymphoma at the Massachusetts General Hospital Cancer Center, and principal investigator of the STARGLO study.

Based on the STARGLO data, this Columvi combination is approved in more than 35 countries, including in the EU, and recommended in clinical practice guidelines including the US National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®).[†3] Data has been submitted to other health authorities around the world for approval consideration. 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.

The sBLA is based on results from the phase III STARGLO study which showed a statistically significant and clinically meaningful 41% reduction in the risk of death (hazard ratio =0.59, 95% confidence interval : 0.40–0.89, p=0.011) in patients treated with Columvi in combination with GemOx.[1] Results were published in *The Lancet* and two-year follow-up data from the study were presented at the 61st American Society of Clinical Oncology Annual Meeting from 30 May – 3 June 2025, where improvements in primary and secondary endpoints were sustained.[1,2]

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.[4] Approximately 160,000 people worldwide are diagnosed with DLBCL each year, with comparable incidence rates across regions.[5,6] Medical practices, including pathological classification, diagnosis, staging, initial treatment and relapse management, are similarly approached worldwide.[6-9] 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.[10,11] 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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Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com