Media & Investor Release

New and updated data for Roche's fixed-duration Columvi and Lunsumio at ASH 2024 reinforce their potential to improve outcomes for people with lymphoma

- **Long-term data confirm fixed-duration Columvi and Lunsumio achieve durable remissions beyond the end of treatment, with real-world data suggesting reduced treatment-related travel burden due to less frequent dosing[1,2,3]**
- **First presentation of Lunsumio given subcutaneously showed non-inferiority to intravenous treatment with a consistent safety profile, potentially providing an additional outpatient option with a shorter administration time[4]**
- **Positive results for Roche's two bispecifics antibodies validate the company's efforts to provide multiple treatment options that suit the diverse needs of lymphoma patients and healthcare providers[5,6]**

Basel, 10 December 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that new and updated data from its industry-leading CD20xCD3 T-cell-engaging bispecific antibody programme were presented at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition, 7-10 December 2024. With more than 20 bispecific antibody abstracts accepted for presentation, data showcase the benefits of fixed-duration Columvi® (glofitamab) and Lunsumio® (mosunetuzumab) across different types of aggressive and indolent lymphomas. This research supports Roche's efforts to continue innovating for patients by advancing treatment standards at earlier stages of disease while exploring additional forms of administration that could further improve the patient experience.

"The data being presented at ASH offer further evidence that Columvi and Lunsumio can provide lasting remissions for people with advanced lymphoma," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The results underscore our ambition to transform the treatment of B-cell malignancies with a range of innovative therapeutic options."

"Lymphoma patients face challenges that extend well beyond the clinical manifestations of their disease, including the physical and emotional strain of frequent appointments and treatments," said Elizabeth Budde, M.D., Ph.D., City of Hope's executive medical director of its Enterprise Immune Effector Cell Program and associate professor in its Division of Lymphoma, Department of Hematology & Hematopoietic Cell Transplantation. "While Lunsumio's fixed duration intravenous formulation has already offered a valuable treatment option, the introduction of a subcutaneous route could provide a shorter administration time. With both routes available, we can better tailor therapy to each patient's needs, supporting a flexible and patient-centered approach to follicular lymphoma care."

Follow-up data reinforce benefits of fixed-duration therapies beyond the end of treatment

Three-year follow-up from the pivotal phase II NP30179 study of Columvi in people with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) showed 40.0% of patients achieved a complete response (CR), with a median duration of CR of 29.8 months (95% CI: 22.0–not estimable [NE]). The majority of patients in complete remission at the end of therapy remained in remission two years after therapy completion. Safety appeared consistent with the previous analysis.[1]

Long-term data at four years from the pivotal phase II GO29781 study of Lunsumio in patients with R/R follicular lymphoma (FL) showed long-lasting remissions, with nearly two-thirds (64.0% [95% CI: 50.1-78.0]) of patients with a CR alive and without disease progression at 45 months. The overall response rate (ORR) and CR rates in the overall population were 77.8% and 60.0%, respectively. Consistent results were seen in patients with a history of disease progression within 24 months of frontline treatment (POD24), which is typically harder to treat. No new safety signals were observed since the previous analysis.[2]

Both studies also showed restoration of B-cell levels, starting from 12-18 months following Columvi treatment and after a median of 19 months following Lunsumio treatment, indicating immune system recovery and supporting the use of a fixed-duration treatment approach.[1,2] Recovery of B cells following treatment for lymphoma is important so that patients can maintain immune system function.

A US real-world data study and economic model evaluating R/R non-Hodgkin lymphoma patient treatment-related travel burden across different bispecific antibody therapies highlight the impact of travel distance, time and associated costs, an often-overlooked aspect of the patient experience beyond clinical efficacy and safety. These factors play a crucial role in treatment decision-making, further emphasising the importance of patient-centred treatment options. The study found fixed-duration therapies, such as Columvi and Lunsumio, reduce treatment-related travel burden due to less frequent dosing.[3]

Studies investigating subcutaneously-administered Lunsumio show positive results

Data from a primary analysis of the phase II GO29781 study of investigational Lunsumio administered subcutaneously in patients with third-line or later FL were presented for the first time. Results show pharmacokinetic non-inferiority compared to intravenous (IV) administration, with fixed-duration Lunsumio achieving high rates of deep and durable remissions, with 76.6% of patients experiencing an ORR and a 61.7% CR rate, as evaluated by the independent review committee. The median progression-free survival was 23.7 months (95% CI: 14.6-NE), while the median overall survival was not reached. The most common all-grade adverse events (AEs) were injection-site reactions (60.6%; all Grade 1-2), fatigue (35.1%), and cytokine release syndrome (CRS; 29.8%). The rate and severity of CRS events

were low (Grade 1-2, 27.6%; Grade 3, 2.1%); all occurred during cycle 1 and were resolved.[4] Data has been submitted to health authorities with the aim of offering patients and healthcare providers an alternative treatment and more choice when it comes to administration options depending on their needs.

New data from a randomised phase II cohort of the investigational GO40516 study showed improved efficacy and manageable safety with outpatient, subcutaneously administered, fixed-duration Lunsumio in combination with Polivy® (polatuzumab vedotin) versus MabThera®/Rituxan® (rituximab) in combination with Polivy, in people with R/R LBCL. In the Lunsumio-Polivy arm, the ORR was 77.5% (95% CI: 61.6-89.2) versus 50.0% (95% CI: 33.8–66.2) for MabThera/Rituxan-Polivy, and the CR rate was 57.5% (95% CI: 40.9-73.0) versus 35.0% (95% CI: 20.6-51.7). AEs of special interest occurring in ≥30% of patients in the Lunsumio-Polivy arm were injection-site reactions (55.0%) and neutropoenia (40.0%). CRS events occurred in four (10.0%) patients, all of which were Grade 1-2, occurred during cycle 1 and were resolved.[5] These data support further exploration of this investigational treatment combination in the ongoing phase III SUNMO study, which could provide an alternative option in second-line DLBCL to meet diverse patient needs.

Additional data support Roche's goal to elevate treatment standards in earlier stages of LBCL

Updated data from the phase I/Ib investigational NP39488 study showed high and durable response rates in people with R/R LBCL treated with Columvi in combination with Polivy, including those with high-grade disease and prior treatment with CAR T-cell therapy. Of the 128 efficacy-evaluable patients, the best ORR was 80.6%, with a CR rate of 62.0%, and the median duration of CR was 31.8 months (95% CI: 21.9-NE). Among patients previously treated with CAR T-cell therapy (n=28), the ORR was 75.0%, with a CR rate of 50.0%. The safety profile was manageable and consistent with the known profiles of the individual drugs. The most common AE was CRS (44.4%), which was mostly Grade 1-2.[6] Results support ongoing development of this investigational combination in the phase III SKYGLO study investigating Columvi with Polivy-MabThera/Rituxan, cyclophosphamide, doxorubicin and prednisone (R-CHP) in previously untreated DLBCL.

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. 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 Lunsumio® (mosunetuzumab)

Lunsumio is a first-in-class CD20xCD3 T-cell-engaging bispecific antibody designed to target CD3 on the surface of T cells and CD20 on the surface of B cells. This dual-targeting activates and redirects a patient's existing T cells to engage and eliminate target B cells by releasing cytotoxic proteins into the B cells. A robust clinical development programme for Lunsumio is ongoing, investigating the molecule as a monotherapy and in combination with other medicines, for the treatment of people with B-cell non-Hodgkin lymphomas, including follicular lymphoma and diffuse large B-cell lymphoma, and other blood cancers.

About Polivy® (polatuzumab vedotin)

Polivy is a first-in-class anti-CD79b antibody-drug conjugate (ADC). The CD79b protein is expressed in the majority of B cells, an immune cell impacted in some types of non-Hodgkin lymphoma (NHL), making it a promising target for the development of new therapies. Polivy binds to cancer cells such as those expressing CD79b and destroys these B cells through the delivery of an anti-cancer agent, which is thought to minimise the effects on normal cells. Polivy is being developed by Roche using Pfizer ADC technology and is currently being investigated for the treatment of several types of NHL.

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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