Media & Investor Release

Roche's Lunsumio and Polivy combination significantly prolongs remission for people with relapsed or refractory large B-cell lymphoma

- **Pivotal phase III SUNMO study demonstrated an 11.5 month median progression-free survival - three times longer than R-GemOx[1]**
- **This well-tolerated investigational combination therapy avoids traditional chemotherapy and may be suitable for outpatient community care**
- **These data demonstrate Roche's commitment to providing options for diverse patient and healthcare system needs in this difficult-to-treat lymphoma**

Basel, 20 June 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) presented today results from the phase III SUNMO [NCT05171647] study showing Lunsumio® (mosunetuzumab) administered subcutaneously in combination with Polivy® (polatuzumab vedotin) demonstrated a clinically meaningful and statistically significant improvement in its primary endpoints of progression-free survival (PFS) and objective response rate (ORR) compared to MabThera®/Rituxan® (rituximab), gemcitabine and oxaliplatin (R-GemOx), in people with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) who are not eligible for transplant.[1] Primary analysis data were featured at the 18th International Conference on Malignant Lymphoma as a late-breaking oral presentation.

Results from the SUNMO study will be submitted to global health authorities, including the US Food and Drug Administration. The National Comprehensive Cancer Network® (NCCN®) has recently added Lunsumio and Polivy to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a category 2A recommendation for the treatment of people with second-line (2L) diffuse large B-cell lymphoma (DLBCL) who are not intended to proceed to transplant.†[2]

"Lunsumio and Polivy represent the first combination of a bispecific antibody and antibody-drug conjugate, which could avoid chemotherapy and potentially provide an alternative option for some patients with relapsed or refractory LBCL," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "We are also encouraged by the favourable safety profile and potential for outpatient use of this regimen, which may suit diverse patient and healthcare system needs."

At a median follow-up of 23.2 months, the Lunsumio and Polivy combination demonstrated a 59% reduction in risk of disease progression or death compared to R-GemOx (hazard ratio [HR] 0.41, 95% confidence interval [CI]: 0.28–0.61; p<0.0001).[1] Median PFS was three times longer with Lunsumio and Polivy at 11.5 months (95% CI: 5.6-17.6), compared to 3.8 months for R-GemOx (95% CI: 2.9-4.1) and 12-month PFS was more than doubled at 48.5% (95% CI:

39.6-57.4) vs.17.8% (95% CI: 5.4-30.3), respectively. This PFS benefit was consistent across subgroups, including in high-risk patients with primary refractory disease (HR 0.46, 95% CI: 0.29–0.72).[1] At the interim analysis, overall survival (OS) data were not yet mature. OS numerically favoured the Lunsumio and Polivy combination with a median of 18.7 months (95% CI: 14.1–not evaluable [NE]) compared to 13.6 months for R-GemOx (95% CI: 9.9–NE; HR 0.80; 95% CI: 0.54 - 1.20).[1]

“There remains a clear need for effective and well-tolerated treatments for people with this difficult-to-treat disease,” said Jason Westin, Professor of Lymphoma and Director of Lymphoma Clinical Research, The University of Texas, MD Anderson Cancer Center. “If approved, this off-the-shelf treatment combination of mosunetuzumab and polatuzumab vedotin could be administered over a fixed period of time, without mandatory hospitalisation or traditional chemotherapy, which could provide a meaningful option for patients with relapsed or refractory LBCL.”

In the Lunsumio and Polivy arm, 30% more patients achieved an objective response (70.3%, 95% CI: 61.9-77.8) compared to R-GemOx (40.0%; 95% CI: 28.5-52.4), and the complete response rate was doubled at 51.4% (95% CI: 42.8-60.0) vs. 24.3% (95% CI: 14.8-36.0).[1] Nearly 75% of patients with a complete response were still in remission after one year (72.6%; 95% CI: 61.4-83.8) compared to 44.1% for R-GemOx (95% CI: 13.2-74.9).[1]

The safety profile of the Lunsumio and Polivy combination was consistent with the known profiles of the individual study medicines, potentially allowing use across outpatient and community settings.[1] The incidence of cytokine release syndrome events (CRS) in the Lunsumio plus Polivy arm was low, occurring in one in four patients, with less than 5% of patients experiencing Grade (Gr) 2 or 3 CRS events.[1] No immune effector cell-associated neurotoxicity syndrome events were reported. Rates of Gr3–4 (58.5% vs. 57.8%) and Gr5 (5.2% vs. 6.3%) adverse events (AEs) were similar between the combination and R-GemOx, with fewer AEs leading to treatment discontinuation in the Lunsumio and Polivy arm (2.2% vs. 4.7%).[1]

High-dose chemotherapy followed by stem-cell transplant has traditionally been the standard 2L treatment for people with R/R LBCL.[3] While 2L therapies have advanced, DLBCL can progress rapidly and many people are not candidates for, cannot tolerate, or do not have access to latest therapies.[2,4] There is an urgent need for treatments that are rapidly available upon a diagnosis of relapse, that can manage the disease and improve long-term outcomes.

Roche’s lymphoma portfolio is one of the broadest in the industry, providing a unique and much-needed opportunity to combine regimens with different and complementary mechanisms of action. We are exploring our CD20xCD3 bispecifics, Lunsumio and Columvi® (glofitamab), alongside Polivy to move one step closer towards our goal of improving the lives

of as many patients with lymphomas as possible. This includes the phase III STARGLO study [NCT04408638] evaluating the efficacy and safety of Columvi in combination with GemOx versus R-GemOx alone in patients with R/R DLBCL 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.

Lunsumio is already approved for people with R/R follicular lymphoma after two or more lines of therapy in more than 60 countries worldwide. Polivy in combination with MabThera/Rituxan, cyclophosphamide, doxorubicin and prednisone is approved for people with previously untreated DLBCL in more than 100 countries worldwide and in combination with bendamustine and MabThera/Rituxan for R/R DLBCL in more than 90 countries worldwide.

About the SUNMO study

The SUNMO [NCT05171647] study is an international, multi-centre, randomised phase III trial evaluating the efficacy and safety of subcutaneously administered Lunsmio® (mosunetuzumab) in combination with intravenous Polivy® (polatuzumab vedotin) compared to MabThera®/Rituxan® (rituximab), gemcitabine and oxaliplatin (R-GemOx), in people with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) who are not eligible for autologous stem cell transplant. Outcome measures include progression-free survival and objective response rate (dual primary endpoints), overall survival, duration of objective response, complete response rate, duration of complete response, safety and tolerability, and patient-reported outcomes.

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, diffuse large B-cell lymphoma, and other indications.

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 large B-cell lymphoma (LBCL)

Large B-cell lymphomas (LBCL), composed predominantly of diffuse large B-cell lymphoma (DLBCL), are the most common type of non-Hodgkin lymphoma (NHL) that affect B-cell lymphocytes, a type of white blood cells. DLBCL is the most common form of aggressive NHL and makes up about 80% of LBCLs. While it can arise in lymph nodes, it can also occur in organs outside of the lymphatic system. Approximately 160,000 people worldwide are diagnosed with DLBCL each year, with comparable incidence rates across regions. Medical practices, including pathological classification, diagnosis, staging, initial treatment and relapse management, are similarly approached worldwide. 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. 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

References

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