Media & Investor Release

Roche presents Lunsumio data showing potential across earlier treatment lines in indolent and aggressive lymphomas

- **Lunsumio in combination with lenalidomide may offer an effective treatment in relapsed or refractory follicular lymphoma based on first data from single-arm US cohort of phase III CELESTIMO study[1]**
- **Data from subcutaneous Lunsumio plus Polivy reinforce its outpatient, chemotherapy-free potential in people with R/R large B-cell lymphoma[2,3]**
- **Results highlight the potential of innovative Lunsumio combination regimens to offer improved outcomes for more people with lymphoma earlier in their disease**

Basel, 8 December 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today new data highlighting the potential of Lunsumio® (mosunetuzumab) in earlier treatment lines for people living with different types of lymphoma, presented at the 67th American Society of Hematology Annual Meeting and Exposition, 6-9 December 2025 in Orlando, Florida, US.

“These data underscore the potential of Lunsumio to support more people living with lymphoma, building on the clinical benefit observed in later-stage follicular lymphoma,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “Moreover, the combinatorial potential of Lunsumio is evident in the two-drug regimens presented, which may enable outpatient treatment while preserving deep and durable efficacy.”

Preliminary data support the potential for Lunsumio in combination with lenalidomide in relapsed or refractory (R/R) follicular lymphoma (FL)[1]
First data from the single-arm US extension of the phase III CELESTIMO study, in 54 patients, demonstrated promising efficacy with this two-drug regimen in people with second-line or later (2L+) FL, including a complete response (CR) rate of 87.0% (95% confidence interval [CI]: 75.1–94.6).[1] Cytokine release syndrome (CRS) events were reported in 27.8% of patients, and were predominantly low grade (Grade (Gr) 1: 22.2%; Gr 2: 3.7%; Gr 3: 1.9%), with all CRS events resolved.[1] Neutropenia occurred in 40.7% of patients, and infections occurred in 57.4% of patients.[1] These results indicate the potential of this combination to deliver meaningful outcomes earlier in the disease course.1 Primary analysis of the pivotal phase III CELESTIMO study is anticipated in 2026.

Lunsumio plus Polivy® (polatuzumab vedotin) data demonstrate meaningful improvements for people with R/R large B-cell lymphoma (LBCL)[2,3]
Long term follow-up data from the phase Ib/II GO40516 study demonstrated sustained improvements in patients treated with Lunsumio subcutaneous (SC) in combination with Polivy compared to those treated with MabThera®/Rituxan® (rituximab) and Polivy in people

with 2L+ LBCL.[2] The overall response rate (ORR) was 77.5% (95% CI: 61.6–89.2) vs 50.0% (95% CI: 33.8–66.2) and median progression-free survival was 25.4 (95% CI: 9.2– not evaluable) vs 6.4 months (95% CI:4.7–18.6).[2] No new safety signals were identified. AEs included neutrophil count decreased/neutropenia (40%), febrile neutropenia (2.5%), infections (45%), and peripheral neuropathy (10%).[2] Patient-reported outcomes from the phase III SUNMO study investigating the same combination, demonstrated benefits across multiple aspects of health-related quality of life measures in comparison to MabThera/Rituxan with gemcitabine and oxaliplatin particularly in maintaining or improving physical functioning, fatigue, lymphoma symptoms and peripheral neuropathy.[3]

Results from these studies highlight the potential of this outpatient combination to prolong remission and improve outcomes for people living with this aggressive disease, without the need for conventional chemotherapy.[2,3]

Long-term follow-up data show sustained responses with fixed-duration Lunsumio SC and intravenous (IV) in third line or later (3L+) FL[4,5]

Five-year follow-up data from the pivotal phase II GO29781 study, the longest reported follow-up for a CD20xCD3 bispecific in R/R FL, showed durable remissions with Lunsumio IV, with a 5-year overall survival rate of 78.5% (95% CI: 69.6–87.4) and 54-month duration of CR rate (DOCR) of 52.0% (95% CI: 36.1-67.9).[4] Furthermore, three-year follow-up data demonstrated durable responses with Lunsumio SC with an ORR of 74.5%, CR rate of 62.8%, and 30-month DOCR of 53.0% (95% CI: 38.7-67.4).[5] No new safety signals were observed in either study.

Lunsumio monotherapy is approved in over 60 countries for people with FL who have received at least two prior systemic therapies, with ongoing discussions with additional health authorities worldwide. Lunsumio SC was recently approved by the European Commission for FL after two or more lines of systemic therapy. A decision from the US Food and Drug Administration is expected soon.

Lunsumio, along with Columvi® (glofitamab), is part of Roche's industry-leading CD20xCD3 bispecific antibody portfolio. Continuing to explore new formulations and combinations of these medicines across different disease areas and lines of treatment is part of Roche's commitment to improve the patient experience and provide more choice to suit diverse patient and healthcare system needs.

About Lunsumio® (mosunetuzumab)

Lunsumio is a first-in-class CD20xCD3 T-cell engaging bispecific antibody designed to target CD20 on the surface of B cells and CD3 on the surface of T 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, other blood cancers and autoimmune disorders.

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 follicular lymphoma (FL)

FL is the most common slow-growing (indolent) form of non-Hodgkin lymphoma, accounting for about one in five cases.[14,15] It typically responds well to treatment but is often characterised by periods of remission and relapse.[14] The disease typically becomes harder to treat each time a patient relapses, and early progression can be associated with poor long-term prognosis.[15] It is estimated that more than 110,000 people are diagnosed with FL each year worldwide.[15,7]

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 the T-cell-engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3 and allogeneic CAR T-cell therapy. 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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