Media & Investor Release

FDA accepts supplemental Biologics License Application for Roche's Lunsumio and Polivy combination for people with relapsed or refractory large B-cell lymphoma

- **Filing acceptance based on data from the phase III SUNMO study where subcutaneous Lunsumio VELO plus Polivy demonstrated a 59% reduction in risk of disease progression or death[1]**
- **People with relapsed or refractory LBCL represent one of the highest unmet need populations in lymphoma and require timely access to effective therapies**
- **If approved, this outpatient-ready regimen could enable access to care in the community setting, where most US patients receive treatment**

Basel, June 18, 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Lunsumio VELO™ (mosunetuzumab), as a subcutaneous formulation, in combination with Polivy® (polatuzumab vedotin) for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL), after at least one prior line of systemic therapy. The FDA is expected to make a decision on approval by 9 February 2027.

The sBLA acceptance is based on results from the phase III SUNMO study. At a median follow-up of 23.2 months, the Lunsumio VELO and Polivy combination demonstrated a 59% reduction in risk of disease progression or death (progression-free survival [PFS]) compared to MabThera®/Rituxan® (rituximab), gemcitabine and oxaliplatin (R-GemOx) (hazard ratio [HR] 0.41, 95% confidence interval [CI]: 0.28–0.61; p<0.0001) and a three-times longer median PFS at 11.5 months (95% CI: 5.6-17.6), compared to 3.8 months for R-GemOx (95% CI: 2.9-4.1).[1] The safety profile of the Lunsumio and Polivy combination was consistent with the known profiles of the individual study medicines.[1] The incidence of cytokine release syndrome events (CRS) in the Lunsumio VELO plus Polivy arm was low, occurring in one in four patients, with less than 5% of patients experiencing Grade 2 or 3 CRS events.[1]

Updated data were presented recently at the American Society of Clinical Oncology Annual Meeting and the European Hematology Association Congress, which showed that with longer follow-up, this treatment combination continued to demonstrate clinical benefit in PFS, particularly in the second-line setting, with no new safety signals.[2,3]

"Relapsed or refractory large B-cell lymphoma is an aggressive disease thereby representing one of the highest unmet needs in lymphoma care," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "If approved, this

Lunsumio/Polivy combination could provide an important chemotherapy-free, outpatient-ready option to help improve outcomes in this setting."

"When treating large B-cell lymphoma, the second-line setting represents a critical window where we must act quickly with effective therapies," said Tara M. Graff, DO, MS, Director of Clinical Research at Mission Cancer and Blood. "Current advanced therapies may present complex logistical and geographical barriers for many patients. Since most patients in the US are treated in the community setting, we need more chemotherapy-free, outpatient-ready treatments, like Lunsumio and Polivy."

LBCL, composed predominantly of DLBCL, is the most common type of non-Hodgkin lymphoma with more than 18,000 new diagnoses each year in the US.[4] 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.[5,6] Because this stage of disease is time-sensitive, delays caused by referral requirements, inpatient coordination, or complex treatment logistics can have meaningful clinical consequences.[7,8]

"Navigating relapsed or refractory large B-cell lymphoma can be challenging, particularly for patients who do not live near a major academic centre," said Meghan Gutierrez, Chief Executive Officer of the Lymphoma Research Foundation. "The potential new Lunsumio VELO and Polivy combination may address this critical access issue by offering treatment options closer to where a patient lives. It fills a gap in care for people who can't afford to travel far distances or for long periods of time for treatment."

Lunsumio is part of Roche's industry-leading CD20xCD3 bispecific antibody programme. It is designed with the unique needs and preferences of patients in mind, offering the possibility of outpatient treatment and flexibility between intravenous (IV) and subcutaneous administration routes. Lunsumio IV and Lunsumio VELO are approved for people with third-line or later follicular lymphoma (FL). Lunsumio holds the most extensive long-term data for any bispecific antibody in lymphoma. Ongoing development of Lunsumio in combination with other treatments includes the phase III CELESTIMO and MorningLyte studies in second-line or later and frontline FL, respectively.

About the SUNMO study

The SUNMO study [NCT05171647] is a phase III, randomised, open-label, multicentre trial evaluating the efficacy and safety of Lunsumio VELO™ (mosunetuzumab) in combination with intravenously administered Polivy® (polatuzumab vedotin) versus MabThera®/Rituxan® (rituximab) plus gemcitabine and oxaliplatin in patients with relapsed or refractory large B-cell lymphoma who have received at least one prior systemic therapy and are ineligible 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 Large B-cell Lymphoma (LBCL)

Large B-cell lymphomas, 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 cell.[5] DLBCL is a highly aggressive and life-threatening disease.[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.[5,6] While existing intensive standard-of-care treatments exist, structural, geographical, and clinical access barriers mean that many patients – particularly those in rural communities or receiving care outside of specialised academic transplant centres – face significant burdens and inequities in obtaining timely treatment.[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 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 malignant B cells. Lunsumio is currently approved as a fixed-duration monotherapy for the treatment of adult patients with third-line or later relapsed or refractory follicular lymphoma (FL) in both intravenous and subcutaneous (Lunsumio VELO™) formulations. A robust, global development programme is ongoing to explore the clinical utility of Lunsumio earlier in the disease course and in novel combinations, including the phase III CELESTIMO trial in second-line or later FL.

About Polivy® (polatuzumab vedotin)

Polivy is a first-in-class antibody-drug conjugate (ADC) targeted against CD79b, a protein preferentially expressed on the surface of mature B cells. Polivy binds to CD79b on the lymphoma cells and delivers a cytotoxic chemotherapy agent directly into the cell, inducing cell death via apoptosis while minimising damage to healthy tissue. Polivy is widely approved globally in combination with MabThera®/Rituxan® (rituximab) plus cyclophosphamide, doxorubicin and prednisone for previously untreated (first-line) diffuse large B-cell lymphoma (DLBCL), as well as in combination with bendamustine and MabThera/Rituxan for relapsed or refractory DLBCL.

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 off-the-shelf allogeneic CAR T-cell therapies. 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

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Lorena Corfas
Phone: +41 79 568 24 95

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +41 79 398 38 53

Yvette Petillon
Phone: +41 79 961 92 50

Dr Rebekka Schnell
Phone: +41 79 205 27 03

Irène Stephan
Phone: +41 79 377 83 75

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