Media & Investor Release

Roche's Lunsumio-based regimen significantly improves progression-free survival in follicular lymphoma in phase III CELESTIMO study

- **Phase III CELESTIMO study met its primary endpoint at the interim analysis demonstrating a statistically significant and clinically meaningful reduction in the risk of disease progression in people with follicular lymphoma who have received at least one prior line of treatment**
- **Data reinforce the potential of this Lunsumio-based regimen to improve clinical outcomes, while offering a tolerable safety profile, simple dosing schedule and outpatient administration**
- **Data will be submitted to health authorities and presented at an upcoming medical meeting**

Basel, 17 September 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the phase III CELESTIMO study evaluating Lunsumio® (mosunetuzumab) in combination with lenalidomide versus MabThera®/Rituxan® (rituximab) plus lenalidomide in people with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least one prior line of treatment met its primary endpoint. Results demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS). Overall survival (OS) data were immature at the time of interim analysis. The safety profile of the Lunsumio and lenalidomide combination was consistent with the known profiles of the individual study medicines, with no new safety signals identified. Data from the study will be submitted to health authorities and presented at an upcoming medical meeting.

"People living with relapsed or refractory follicular lymphoma need treatment options that provide meaningful clinical benefit and minimal disruptions to everyday care," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The CELESTIMO results indicate that a two-drug outpatient Lunsumio regimen may offer these patients an effective new option earlier in their treatment journey."

CELESTIMO is a confirmatory study required to convert the accelerated approval/conditional marketing authorisation of Lunsumio monotherapy for third-line or later (3L+) FL to full approval, as well as to secure an indication in second-line or later (2L+) FL.

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 and subcutaneous administration routes. Lunsumio is already approved for people with 3L+ FL in 60 countries worldwide and has been used to treat over 3,800 patients.[1]

Roche Holding Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

With the longest follow-up data of any bispecific antibody in lymphoma and a broad clinical development programme spanning multiple disease settings, including both FL and diffuse large B-cell lymphoma (DLBCL), Lunsumio is helping redefine care across B-cell malignancies. The U.S. Food and Drug Administration (FDA) recently accepted the supplemental Biologics License Application (sBLA) for Lunsumio in combination with Polivy® (polatuzumab vedotin) for 2L+ DLBCL based on the SUNMO study, and results from CELESTIMO support continued expansion of Lunsumio and lenalidomide into earlier FL treatment, with the phase III MorningLyte study ongoing in first-line FL.

About the CELESTIMO study

CELESTIMO [NCT04712097] is a phase III trial evaluating the efficacy and safety of Lunsumio® (mosunetuzumab) in combination with lenalidomide vs. MabThera®/Rituxan® (rituximab) plus lenalidomide in people with relapsed or refractory follicular lymphoma (FL) who have received at least one line of prior systemic therapy. It is a confirmatory study required to convert the accelerated approval/conditional marketing authorisation of Lunsumio monotherapy for third-line or later FL to full approval, as well as to secure an indication in second-line or later FL.

About follicular lymphoma

Follicular lymphoma (FL) is the most common slow-growing (indolent) form of non-Hodgkin lymphoma, accounting for about one in five cases.[2] It typically responds well to treatment but is often characterised by periods of remission and relapse.[3] The disease typically becomes harder to treat each time a patient relapses, and early progression can be associated with poor long-term prognosis.[4] It is estimated that more than 110,000 people are diagnosed with FL each year worldwide.[5]

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 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. 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.

References

[1] Roche data on file.
[2] Lymphoma Research Foundation. About Follicular Lymphoma. [Internet; cited September 2026]. Available from: https://lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/follicular-lymphoma/
[3] Lymphoma Action. Follicular Lymphoma. [Internet; cited September 2026]. Available from: https://lymphoma-action.org.uk/types-lymphoma-non-hodgkin-lymphoma/follicular-lymphoma
[4] Skarbnik AZ et al. Treatment selection for patients with relapsed or refractory follicular lymphoma. Front Oncol. 2023;13:1120358.
[5] World Health Organization. Numbers derived from GLOBOCAN 2022. Non-Hodgkin Lymphoma Factsheet [Internet; cited September 2026]. Available from: https://gco.iarc.who.int/media/globocan/factsheets/cancers/34-non-hodgkin-lymphoma-fact-sheet.pdf.

Roche Holding Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Roche Global Media Relations

Phone: +41 61 688 88 88 / e-mail: media.relations@roche.com

Tristan Schmitz
Phone: +41 79 529 70 35

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

Irène Stephan
Phone: +41 79 377 83 75

Albert Thottiyil
Phone: +41 79 775 66 12

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