Media & Investor Release

New data for Roche's Columvi and Lunsumio presented at ASH 2023 support continued benefit for people with lymphoma

- **Longer-term data from pivotal studies of fixed-duration Columvi and Lunsumio continue to show durable responses in people with heavily pre-treated lymphomas[1,2]**
- **New data reinforce the potential of combination regimens in earlier treatment settings and add to the robust body of evidence supporting ongoing Phase III studies[3,4,5,6]**

Basel, 11 December 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that new data from its CD20xCD3 T-cell engaging bispecific antibody programme, including eight oral presentations, were presented at the 65th American Society of Hematology (ASH) Annual Meeting & Exposition, 9-12 December 2023. Based on 32-month and 3-year follow-ups of two pivotal studies for fixed-duration treatments of Columvi® (glofitamab) and Lunsumio® (mosunetuzumab), respectively, data show that remissions were maintained in the majority of patients with heavily pre-treated lymphomas.[1,2] Additionally, new early-phase data of novel Columvi or Lunsumio combination regimens support ongoing investigation in Phase III studies in earlier lines of diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL).[3,4,5,6]

"Updated data from pivotal studies of Columvi and Lunsumio continue to provide compelling evidence for how fixed-duration therapies can deliver sustained, long-term benefit for people with difficult-to-treat lymphomas," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Our data at ASH also demonstrate progress in evaluating our bispecific antibodies in earlier stages of disease and additional types of lymphoma so more people can benefit from our therapies."

Longer follow-up data from pivotal studies of fixed-duration Columvi and Lunsumio show benefit is maintained beyond the end of treatment

Extended follow-up data from the pivotal Phase II NP30179 study of Columvi administered for up to 12 cycles (approximately eight months) in patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) who have received at least two prior lines of therapy showed favourable long-term outcomes. After a median follow-up of 32 months, 55% of patients with a complete response (CR) were in remission at 24 months. Most of these patients remained progression-free and alive 18 months after completing the fixed-duration treatment. In patients who had received prior chimeric antigen receptor (CAR) T-cell therapy, the median duration of CR was 22.0 months (95% confidence interval [CI]: 6.7–not reached). No new safety signals were observed since the previous analysis.[1]

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Data from a three-year follow-up analysis of the pivotal Phase II GO29781 study of Lunsumio in patients with R/R FL who have received at least two prior lines of therapy were presented. Results showed continued durable responses and a manageable safety profile after treatment (up to approximately 12 months), with 59% of patients completing treatment after eight cycles (approximately five months). 72.7% of the patients with a CR were alive and without disease progression, 30 months after their first response. In the overall population, median progression-free survival (PFS) was 24 months (95% CI: 12.0–not evaluable [NE]) and overall survival (OS) was not yet reached. No new safety signals were observed since the previous analysis.[2]

Additional data presented reinforce the potential of novel combination regimens in earlier treatment settings

Diffuse large B-cell lymphoma

Data from the Phase Ib/II GO40516 study of Lunsumio plus Polivy® (polatuzumab vedotin) in patients with R/R LBCL were presented and simultaneously published in *Nature Medicine*.[3,7] Results showed that at 24 months median follow-up, the median PFS was 11.4 months (95% CI: 6.2–18.7), and median OS was 23.3 months (95% CI: 14.8–NE), highlighting the combination's potential in R/R LBCL. The overall safety profile of patients with R/R LBCL treated with Lunsumio plus Polivy was manageable. Cytokine release syndrome (CRS) events were generally low grade (Grade 1: 10.2%; Grade 2: 5.1%; Grade 3: 3.1%).[3] Lunsumio in combination with Polivy is being evaluated as an outpatient therapy for patients with R/R DLBCL in the ongoing Phase III SUNMO study.

Results from both arms of the Phase Ib NP40126 study evaluating Columvi in combination with MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP), and Columvi in combination with Polivy plus MabThera/Rituxan, cyclophosphamide, doxorubicin and prednisone (Pola+R-CHP) in previously untreated DLBCL were presented. After a median of 12 months follow-up, data from the Columvi plus Pola+R-CHP arm showed that 91.7% of patients had a CR with no progression observed. Of the patients with a CR, 95.5% were still in remission, with a 12-month PFS rate of 91.5%. Safety profiles were highly consistent with earlier analyses from this study.[4] These data support the ongoing Phase III SKYGLO study in previously untreated DLBCL.

Follicular lymphoma

The Phase II MorningSun study, evaluating a subcutaneous (SC) formulation of Lunsumio in patients with selected B-cell non-Hodgkin lymphomas, showed that SC Lunsumio is active and has a manageable safety profile in patients with first-line (1L) low-tumour burden FL. Data showed that 83.3% of patients achieved a complete metabolic response (95% CI: 62.6-95.3) and responses were ongoing at data cut-off. CRS was generally low grade (Grade 1: 36.7%;

Grade 2: 6.7%) and occurred in cycle one only.[5] Subcutaneous Lunsumio is also being investigated in combination with oral lenalidomide in 1L FL in the Phase Ib/II CO41942 study. New data demonstrated promising efficacy and manageable safety; data showed that 89.2% of patients achieved a CR and CRS events were either Grade 1 (47.5%) or 2 (2.5%), all of which were confined to cycles one to two.[6] The data support further investigation of this SC formulation of Lunsumio and highlight its potential as a tailored monotherapy or combination outpatient therapy for FL, including in community practices.[5,6]

Totality of data presented underscores the strength of Roche's broad, industry-leading development programme, which aims to address the diverse needs, preferences and experiences of people with blood cancers

Both Columvi and Lunsumio are being investigated in Phase III studies that will expand the understanding of their impact in earlier lines of treatment. This includes the Phase III STARGLO study evaluating Columvi in combination with GemOx in patients with R/R DLBCL who are ineligible for autologous stem cell transplant; the Phase III SKYGLO study evaluating the efficacy and safety of Columvi plus Pola+R-CHP in previously untreated DLBCL; the Phase III GLOBRYTE study evaluating Columvi monotherapy in R/R mantle cell lymphoma; the Phase III SUNMO study investigating Lunsumio plus Polivy in R/R DLBCL; and the Phase III CELESTIMO study investigating Lunsumio plus lenalidomide in patients with R/R FL.

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. A clinical development programme for Columvi 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 diffuse large B-cell lymphoma and other blood cancers.

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 Seagen 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 20 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), Lunsumio® (mosunetuzumab) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3, Tecentriq® (atezolizumab), and crovalimab, an anti-C5 antibody engineered to optimise complement inhibition. 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.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

References

[1] Hutchings M, et al. Glofitamab Monotherapy in Relapsed or Refractory Large B-Cell Lymphoma: Extended Follow-Up from a Pivotal Phase II Study and Subgroup Analyses in Patients with Prior Chimeric Antigen Receptor T-Cell Therapy and by Baseline Total Metabolic Tumor Volume. Presented at: ASH Annual Meeting and Exposition; 2023 Dec 9-12. Abstract #433.
[2] Schuster S, et al. Mosunetuzumab Monotherapy Continues to Demonstrate Durable Responses in Patients with Relapsed and/or Refractory Follicular Lymphoma after ≥2 Prior Therapies: 3-Year Follow-up from a Pivotal Phase II Study. Presented at: ASH Annual Meeting and Exposition; 2023 Dec 9-12. Abstract #603.
[3] Budde E, et al. Mosunetuzumab Plus Polatuzumab Vedotin Demonstrates a Favorable Safety Profile and Efficacy in Patients (Pts) with Relapsed or Refractory (R/R) Large B-Cell Lymphoma (LBCL): Primary Analysis of a Phase Ib/II Study. Presented at: ASH Annual Meeting and Exposition; 2023 Dec 9-12. Abstract #613.
[4] Topp M, et al. Glofitamab Plus R-CHOP Induces High Response Rates with a Manageable Safety Profile in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL): A 12-Month Analysis from a Phase Ib Study. Presented at: ASH Annual Meeting and Exposition; 2023 Dec 9-12. Abstract #3085.
[5] Flinn I, et al. Subcutaneous Mosunetuzumab Is Active and Has a Manageable Safety Profile in Patients with Previously Untreated, Low-Tumor Burden Follicular Lymphoma: Initial Results from the Phase II Morningsun Study. Presented at: ASH Annual Meeting and Exposition; 2023 Dec 9-12. Abstract #3029.
[6] Morschhauser F, et al. Preliminary Findings of a Phase Ib/II Trial Indicate Manageable Safety and Promising Efficacy for Mosunetuzumab in Combination with Lenalidomide (M+Len) in Previously Untreated (1L) Follicular Lymphoma (FL). Presented at: ASH Annual Meeting and Exposition; 2023 Dec 9-12. Abstract #605.
[7] Budde LE et al. Mosunetuzumab with polatuzumab vedotin in relapsed or refractory aggressive large B cell lymphoma: a phase 1b/2 trial. Nature Medicine. 2023. https://doi.org/10.1038/s41591-023-02726-5

F. Hoffmann-La Roche 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 8888 / e-mail: media.relations@roche.com

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

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Nina Mählitz
Phone: +41 79 327 54 74

Kirti Pandey
Phone: +49 172 6367262

Dr. Rebekka Schnell
Phone: +41 79 205 27 03

Sileia Urech
Phone: +41 79 935 81 48

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

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com