Media & Investor Release

Roche to present new and encouraging long-term follow-up data across broad haematology portfolio at ASH 2024

Basel, 05 November 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it will present more than 40 abstracts across nine blood disorders at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition, held 7-10 December 2024 in San Diego, US. The data underscore Roche's commitment to advance patient outcomes in lymphoma with long-term follow-up of its approved medicines Polivy® (polatuzumab vedotin), Lunsumio® (mosunetuzumab) and Columvi® (glofitamab) as well as new investigational combination data.

Key presentations include:

- Five-year data from the phase III POLARIX study (abstract #469) reinforce the potential of Polivy in combination with MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) to provide durable and lasting remissions and for the first time show a positive trend in overall survival (OS) for people with first-line diffuse large B-cell lymphoma (DLBCL), an area that previously had little advancement in nearly two decades.[1]
- Extended follow-up data of up to four years from the pivotal GO29781 study of Lunsumio (abstract #4407) and NP30179 study of Columvi (abstract #865) show long-lasting remissions and immune system recovery after the end of treatment, supporting the use of fixed-duration bispecific antibodies for third line or later (3L+) follicular lymphoma (FL) and DLBCL respectively.[2,3]
- First presentation of data for a subcutaneous formulation of Lunsumio monotherapy from the pivotal phase II GO29781 study (abstract #1645) show high rates of deep and durable responses and low rates and severity of cytokine release syndrome in people with 3L+ FL.[4] Subcutaneously administered Lunsumio could further improve the patient experience by combining shorter administration time with the existing benefits of a fixed-duration and outpatient therapy.
- New patient-reported outcomes data from the phase III STARGLO study (abstract #5132) indicate comparable health-related quality of life between treatment arms, despite higher median number of cycles received with the Columvi combination (11 versus 4).[5] Together with the significant improvement in OS observed in the study, these data support the potential benefit for patients with second-line or later DLBCL.
- New and updated data from investigational study combinations of Polivy with bispecific antibodies Lunsumio and Columvi in relapsed or refractory DLBCL, including the phase Ib/II NP39488 (abstract #988) and phase II GO40516 (abstract #989) studies, add to the growing body of evidence demonstrating the potential of novel

bispecific antibody/Polivy combinations in earlier treatment lines, and support their ongoing phase III development.[6,7]

Overview of key presentations featuring Roche medicines

Medicine	Abstract title	Abstract number/presentation details
Polivy® (polatuzumab vedotin)	Five-Year Analysis of the POLARIX Study: Prolonged Follow-up Confirms Positive Impact of Polatuzumab Vedotin Plus Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (Pola-R-CHP) on Outcomes	#469 oral presentation Session: 626. Aggressive Lymphomas: Clinical and Epidemiological: CARs, Bispecifics, and ADCs: Progress and Challenges in Aggressive B Cell Lymphoma Sunday 8 December 2024 9.30am PST
	A Multicenter, Prospective, Observational Study of Pola-R-CHP in Patients With Previously Untreated Diffuse Large B-Cell Lymphoma (POLASTAR): A Preliminary Analysis	#4475 poster presentation Session: 626. Aggressive Lymphomas: Clinical and Epidemiological: Poster III Monday 9 December 2024 6pm-8pm PST
Lunsumio® (mosunetuzumab)	A Randomized Phase II Study of Mosunetuzumab SC Plus Polatuzumab Vedotin Demonstrates Improved Outcomes Versus Rituximab Plus Polatuzumab Vedotin in Patients (Pts) with Relapsed or Refractory (R/R) Large B-Cell Lymphoma (LBCL)	#989 oral presentation Session: 627. Aggressive Lymphomas: Pharmacologic Therapies: Chemotherapy-free Combinations for Relapsed Aggressive Lymphomas Monday 9 December 2024

		5.30pm PST
	Subcutaneous Mosunetuzumab Leads to High Rates of Durable Responses, Low Rates of Cytokine Release Syndrome, and Non-Inferior Exposure Compared with Intravenous Administration in Patients with Relapsed/Refractory Follicular Lymphoma: Primary Analysis of a Pivotal Phase II Study	#1645 poster presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster I Saturday 7 December 2024 5.30pm-7.30pm PST
	Mosunetuzumab Continues to Demonstrate Clinically Meaningful Outcomes in Patients with Relapsed and/or Refractory Follicular Lymphoma after ≥2 Prior Therapies Including Those with a History of POD24: 4-Year Follow-up of a Pivotal Phase II Study	#4407 poster presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III Monday 9 December 2024 6pm-8pm PST
	Mosunetuzumab Monotherapy Demonstrates Encouraging Activity and a Manageable Safety Profile in Patients with Heavily Pre-Treated Relapsed or Refractory Mantle Cell Lymphoma	#1646 poster presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster I Saturday 7 December 2024 5.30pm-7.30pm PST
	Fixed-Duration Subcutaneous Mosunetuzumab is Active and has a Manageable Safety Profile in Patients with	#3008 poster presentation

	Previously Untreated, Low-Tumor Burden Follicular Lymphoma: Updated Results from the Phase II MorningSun Study	Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster II Sunday 8 December 2024 6pm-8pm PST
	Travel Burden and Travel Costs of Bispecific Antibodies in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma and Relapsed/Refractory Follicular Lymphoma	#782 oral presentation Session: 902. Health Services and Quality Improvement: Lymphoid Malignancies: For a Better Tomorrow - Improving Access to Blood Cancer Treatments and Trials Monday 9 December 2024 10.45am PST
Columvi® (glofitamab)	Fixed-duration Glofitamab Monotherapy Continues to Demonstrate Durable Responses in Patients with Relapsed or Refractory Large B-Cell Lymphoma: 3-year Follow-Up From a Pivotal Phase II Study	#865 oral presentation Session: 627. Aggressive Lymphomas: Pharmacologic Therapies: New R-CHOP Combinations for Treatment Naïve DLBCL Sunday 8 December 2024 Midday PST
	Glofitamab in Combination with Polatuzumab Vedotin Maintains Durable Responses and a Manageable Safety Profile in Patients with Heavily Pre-treated Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Including High-Grade B-	#988 oral presentation Session: 627. Aggressive Lymphomas: Pharmacologic Therapies: Chemotherapy-free

	Cell Lymphoma (HGBCL): Extended Follow-Up of a Phase Ib/II Study	Combinations for Relapsed Aggressive Lymphomas Monday 9 December 2024 5.15pm PST
	Glofitamab in Combination with Rituximab plus Ifosfamide, Carboplatin, and Etoposide shows Favorable Efficacy and Manageable Safety in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma, Eligible for Stem Cell Transplant or Chimeric Antigen Receptor T-cell Therapy: Results from a Phase Ib Study	#987 oral presentation Session: 627. Aggressive Lymphomas: Pharmacologic Therapies: Chemotherapy-free Combinations for Relapsed Aggressive Lymphomas Monday 9 December 2024 5pm PST
	Primary Results of Patient-Reported Outcomes in Patients with Relapsed/Refractory Diffuse Large B-cell Lymphoma Treated with Glofitamab plus Gemcitabine and Oxaliplatin (Glofit-GemOx) Versus Rituximab plus GemOx (R-GemOx) from the Phase III STARGLO Study	#5132 poster presentation Session: 906. Outcomes Research: Lymphoid Malignancies Excluding Plasma Cell Disorders: Poster III Monday 9 December 2024 6pm-8pm PST
	Glofitamab Induces High Response Rates and Durable Remissions in Patients (Pts) with Heavily Pretreated Relapsed/Refractory (R/R) Mantle Cell Lymphoma (MCL), including those with a Poor Prognosis: Subgroup Results from a Phase I/II Study	#1631 poster presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster I Saturday 7 December 2024

		5.30pm-7.30pm PST
	A Healthcare Utilization Model Comparing Time Toxicity Between Glofitamab and Epcoritamab Treatment Regimens	#3647 poster presentation Session: 902. Health Services and Quality Improvement: Lymphoid Malignancies: Poster II Sunday 8 December 2024 6pm-8pm PST
Englumafusp alfa	Englumafusp alfa (CD19-4-1BBL) combined with glofitamab is safe and efficacious in patients with r/r B-NHL: extended follow up analysis of the dose-escalation part of Phase 1 trial BP41072	#990 oral presentation Session: 627. Aggressive Lymphomas: Pharmacologic Therapies: Chemotherapy-free Combinations for Relapsed Aggressive Lymphomas Monday 9 December 2024 5.45pm PST
Cevostamab	Cevostamab in Patients with Heavily Pretreated Relapsed/Refractory Multiple Myeloma (RRMM): Updated Results from an Ongoing Phase I Study Demonstrate Clinically Meaningful Activity and Manageable Safety and Inform the Doses and Regimen for Combination Studies	#1021 oral presentation Session: 654. Multiple Myeloma: Pharmacologic Therapies: Into the Future: New Drugs and Combinations in Multiple Myeloma Monday 9 December 2024 4.30pm PST
Venclexta®/Venclyxto® (venetoclax)*	CRISTALLO: Results from a Phase III Trial of Venetoclax–Obinutuzumab versus	#3237 poster presentation

	Fludarabine, Cyclophosphamide and Rituximab or Bendamustine–Rituximab in Patients with Untreated Chronic Lymphocytic Leukemia Without Del(17p) or TP53 Mutations	Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster II Sunday 8 December 2024 6pm-8pm PST
P-CD19CD20-ALLO1 (in collaboration with Poseida Therapeutics)	P-CD19CD20-ALLO1: Potent Fully Allogeneic CAR-T Therapy Targeting CD19 and CD20 with Superior Efficacy Over Single-Target Products	#4805 poster presentation Session: 702. CAR-T Cell Therapies: Basic and Translational: Poster III Monday 9 December 2024 6pm-8pm PST
P-BCMA-ALLO1 (in collaboration with Poseida Therapeutics)	A Phase 1 Study of P-BCMA-ALLO1, a Non-viral, Allogeneic BCMA Directed CAR-T in Relapsed/Refractory Multiple Myeloma (RRMM): Results from Optimized Lymphodepletion Cohort	#4828 poster presentation Session: 704. Cellular Immunotherapies: Early Phase Clinical Trials and Toxicities: Poster III Monday 9 December 2024 6pm-8pm PST
Hemlibra® (emicizumab)	Bleed Patterns in Infants, From Birth to 12 Months of Age, with Hemophilia A Treated with Emicizumab: Exploratory Analysis of the HAVEN 7 Study	#1214 poster presentation Session: 322. Hemophilia A and B: Clinical and Epidemiological: Poster I Saturday 7 December 2024 5.30pm-7.30pm PST

	Real-World Experience With Emicizumab for Hemophilia A From the Physician Perspective Based on Survey Data	#5078 poster presentation Session: 905. Outcomes Research: Non-Malignant Conditions Excluding Hemoglobinopathies: Poster III Monday 9 December 2024 6pm-8pm PST
PiaSky® (crovalimab)	Phase III Randomized COMMODORE 2 Trial: 2-Year Efficacy and Safety of Crovalimab in Patients With Paroxysmal Nocturnal Hemoglobinuria (PNH) Naive to Complement Inhibition	#2687 poster presentation Session: 508. Bone Marrow Failure: Acquired: Poster II Sunday 8 December 2024 6pm-8pm PST
	Phase III COMMODORE 1 Trial: 2-Year Efficacy and Safety of Crovalimab in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Who Switched from Ravulizumab	#4078 poster presentation Session: 508. Bone Marrow Failure: Acquired: Poster III Monday 9 December 2024 6pm-8pm PST

**Venclexta/Venclyxto is being developed by AbbVie and Roche. It is jointly commercialised by AbbVie and Genentech, a member of the Roche Group, in the US, and commercialised by AbbVie outside of the US.*

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.

References

[1] Salles G, et al. Five-Year Analysis of the POLARIX Study: Prolonged Follow-up Confirms Positive Impact of Polatuzumab Vedotin Plus Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (Pola-R-CHP) on Outcomes. Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #469.
[2] Shadman M, et al. Mosunetuzumab Continues to Demonstrate Clinically Meaningful Outcomes in Patients with Relapsed and/or Refractory Follicular Lymphoma after ≥2 Prior Therapies Including Those with a History of POD24: 4-Year Follow-up of a Pivotal Phase II Study. Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #4407.
[3] Dickinson M, et al. Fixed-duration Glofitamab Monotherapy Continues to Demonstrate Durable Responses in Patients with Relapsed or Refractory Large B-Cell Lymphoma: 3-year Follow-Up From a Pivotal Phase II Study. Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #865.
[4] Bartlett N, et al. Subcutaneous Mosunetuzumab Leads to High Rates of Durable Responses, Low Rates of Cytokine Release Syndrome, and Non-Inferior Exposure Compared with Intravenous Administration in Patients with Relapsed/Refractory Follicular Lymphoma: Primary Analysis of a Pivotal Phase II Study. Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #1645.
[5] Gregory G, et al. Primary Results of Patient-Reported Outcomes in Patients with Relapsed/Refractory Diffuse Large B-cell Lymphoma Treated with Glofitamab plus Gemcitabine and Oxaliplatin (Glofit-GemOx) Versus

Rituximab plus GemOx (R-GemOx) from the Phase III STARGLO Study. Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #5132.
[6] Hutchings M, et al. Glofitamab in Combination with Polatuzumab Vedotin Maintains Durable Responses and a Manageable Safety Profile in Patients with Heavily Pre-treated Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Including High-Grade B-Cell Lymphoma (HGBCL): Extended Follow-Up of a Phase Ib/II Study. Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #988.
[7] Chavez J, et al. A Randomized Phase II Study of Mosunetuzumab SC Plus Polatuzumab Vedotin Demonstrates Improved Outcomes Versus Rituximab Plus Polatuzumab Vedotin in Patients (Pts) with Relapsed or Refractory (R/R) Large B-Cell Lymphoma (LBCL). Presented at: ASH Annual Meeting; 2024 Dec 7-10; San Diego, CA, USA. Abstract #989.

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