Media & Investor Release

Roche to present new data from its broad and innovative haematology portfolio at ASH 2025

- **Findings further demonstrate the effectiveness of Roche's approved medicines in advancing treatment standards for people with blood disorders**

- **Data from innovative pipeline signals progress toward improved outcomes in haemophilia A, lymphoma, and multiple myeloma**

Basel, 3 November 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it will showcase 46 abstracts, including 12 oral presentations, from its industry-leading haematology portfolio at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition, held 6-9 December 2025 in Orlando, Florida, US.

"The data we will present at this year's ASH meeting underscore our commitment to driving innovation across haematology and reflect meaningful progress towards improved treatment of multiple blood disorders," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development.

Key presentations include:

Haemophilia A

- Hemlibra® (emicizumab): New post-marketing data from the Beyond ABR study show that, in the first year after switching to Hemlibra prophylaxis from factor VIII prophylaxis, people with various levels of baseline joint impairment had low bleeding rates, associated with overall improvements in joint health, and a shift towards higher activity levels.[1] These findings add to the wealth of clinical and real-world evidence in support of Hemlibra as it continues to redefine standards of care for people living with haemophilia A.[2-11]
- NXT007: Positive phase I/II results, including new data from a global study in people with haemophilia A with and without factor VIII inhibitors, suggest the potential of Roche's next-generation investigational bispecific antibody to normalise haemostasis.[12-14] These data support the progression of NXT007 into phase III clinical development planned for 2026, including a head-to-head study against Hemlibra.
- SPK-8011QQ: Pre-clinical data on Roche's next-generation investigational AAV gene therapy, show significantly enhanced haemostatic potency compared with SPK-8011 (dirloctocogene samoparvovec) in ex vivo and in vivo mouse models.[15] Findings support the ongoing evaluation of SPK-8011QQ, furthering previous learnings on the safety and durability of SPK-8011, with phase IIb study initiation planned for 2026.

Lymphoma

- Lunsumio® (mosunetuzumab): Preliminary data from the US extension arm of the phase III CELESTIMO study investigating Lunsumio plus lenalidomide, in people with second-line or later (2L+) relapsed or refractory (R/R) follicular lymphoma (FL), support its potential as an effective and well-tolerated outpatient treatment option.[16]
- Lunsumio plus Polivy® (polatuzumab vedotin): Long-term follow-up data from the phase Ib/II GO40516 study demonstrate sustained improvements in objective response rate (ORR) and progression-free survival with this combination in people with 2L+ large B-cell lymphoma (LBCL).[17] Additionally, patient-reported outcomes from the phase III SUNMO study show treatment with Lunsumio plus Polivy was associated with delayed deterioration in physical function and improvements in fatigue, pain, and emotional function, in people with transplant-ineligible R/R LBCL.[18]
- Columvi® (glofitamab): Three-year follow-up and subgroup analyses from the phase III STARGLO study show continued superior survival outcomes with Columvi in combination with gemcitabine and oxaliplatin (GemOx) for people with R/R diffuse large B-cell lymphoma (DLBCL) compared with MabThera®/Rituxan® (rituximab) and GemOx, including people with second-line DLBCL and primary refractory disease or early relapse.*[19-20]

Multiple myeloma

- Cevostamab: Clinical and exploratory biomarker analysis from the phase Ib CAMMA-1 study shows investigational cevostamab in combination with pomalidomide and dexamethasone induces high ORR, very good partial response (VGPR) or better rates, and durable remissions, in R/R multiple myeloma.[21]
- First data from the phase Ib CAMMA-3 study highlight that subcutaneous cevostamab monotherapy delivers deep and durable responses in people with late-line R/R multiple myeloma.[22]
- These data support the progression of cevostamab in combination with pomalidomide and dexamethasone into phase III clinical development for people with 2L+ R/R multiple myeloma, with study initiation planned for 2026.

Overview of key presentations featuring Roche medicines

Medicine	Abstract title	Abstract number/presentation details
cevostamab	Tumor clearance, T-cell fitness and minimal residual disease (MRD) outcomes in patients with relapsed/refractory multiple myeloma (RRMM) treated with cevostamab plus pomalidomide and dexamethasone: Biomarker analyses from CAMMA 1 arm b	#252 oral presentation Session: 654. Multiple Myeloma: Pharmacologic Therapies: Advances in Treatment Strategies for Relapsed/Refractory Multiple Myeloma Saturday 6 December 2025 3:15pm EST
	Subcutaneous cevostamab demonstrates manageable safety and clinically meaningful activity in relapsed/refractory multiple myeloma (RRMM): First results from the phase Ib CAMMA 3 study	#700 oral presentation Session: 654. Multiple Myeloma: Pharmacologic Therapies: Bi, Tri and Beyond: Innovations in Bispecific and Trispecific Antibodies for Multiple Myeloma Sunday 7 December 2025 5:15pm EST
Columvi® (glofitamab)	CRS-RS.5p predictive model informs risk stratification and cytokine release syndrome management following glofitamab treatment in patients with relapsed or refractory diffuse large B-cell lymphoma	#2559 poster presentation Session: 803. Emerging Tools, Techniques, and Artificial Intelligence in Hematology: Poster I Saturday 6 December 2025 5:30pm-7:30pm EST
	Glofitamab plus gemcitabine and oxaliplatin (GemOx) vs rituximab (R)-	#3743 poster presentation

	GemOx in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): efficacy and safety in patient subgroups	Session: 629. Aggressive Lymphomas, Immunotherapy including Bispecific Antibodies: Poster II Sunday 7 December 2025 6pm-8pm EST
	Glofitamab in combination with polatuzumab vedotin demonstrates high and durable efficacy in patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) in the second-line (2L) and third-line and later (3L+) setting: A subgroup analysis	#5510 poster presentation Session: 629. Aggressive Lymphomas, Immunotherapy including Bispecific Antibodies: Poster III Monday 8 December 2025 6pm-8pm EST
	Sustained clinical benefit of glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab plus GemOx (R-GemOx) in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): 3-year follow-up of STARGLO	#5519 poster presentation Session: 629. Aggressive Lymphomas, Immunotherapy including Bispecific Antibodies: Poster III Monday 8 December 2025 6pm-8pm EST
Hemlibra® (emicizumab)	Evolution of joint health and physical activity in people with hemophilia A without factor VIII inhibitors switching to emicizumab prophylaxis: A second interim analysis of the BEYOND ABR study	#1285 poster presentation Session: 322. Hemophilia A and B: Clinical and Epidemiological: Poster III Saturday 6 December 2025 5:30pm-7:30pm EST

Lunsumio® (mosunetuzumab)	Fixed treatment duration subcutaneous mosunetuzumab monotherapy in elderly/unfit patients with previously untreated diffuse large B-cell lymphoma: Interim results from the Phase II MorningSun study	#62 oral presentation Session: 629. Aggressive Lymphomas, Immunotherapy including Bispecific Antibodies: Overcoming Barriers in Frontline Therapy: Bispecific Antibodies for Older Adults with DLBCL Saturday 6 December 2025 9:45am EST
	Fixed-duration subcutaneous (SC) mosunetuzumab, with maintenance therapy, in patients (pts) with previously untreated high-tumor burden follicular lymphoma (HTB FL): Longer follow-up and exploratory circulating tumor (ct)DNA analysis of the Phase II MorningSun study	#228 oral presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: FL and WM Saturday 6 December 2025 3:15pm EST
	Long-term follow-up with sustained progression-free survival (PFS) benefit after subcutaneous (SC) mosunetuzumab in combination with polatuzumab vedotin compared with rituximab plus polatuzumab vedotin in patients with relapsed or refractory (R/R) B-cell non-Hodgkin Lymphoma	#1020 oral presentation Session: 629. Aggressive Lymphomas, Immunotherapy including Bispecific Antibodies: Improving Outcomes in Rare Large Cell Lymphomas Monday 8 December 2025 5:45pm EST
	Promising response rates and manageable safety with mosunetuzumab plus	#1800 poster presentation

	lenalidomide (Mosun-Len) in patients with relapsed/refractory (R/R) follicular lymphoma (FL): US extension cohort from the Phase III CELESTIMO study	Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster I Saturday 6 December 2025 5:30pm-7:30pm EST
	Improvements in health-related quality of life (HRQoL) in the SUNMO study: subcutaneous (SC) mosunetuzumab plus polatuzumab vedotin (Mosun-Pola) versus rituximab, gemcitabine and oxaliplatin (R-GemOx) in patients (pts) with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) after at least one prior therapy	#5509 poster presentation Session: 629. Aggressive Lymphomas, Immunotherapy including Bispecific Antibodies: Poster III Monday 8 December 2025 6pm-8pm EST
	Fixed treatment duration mosunetuzumab continues to demonstrate clinically meaningful outcomes in patients with relapsed/refractory (R/R) follicular lymphoma (FL) after ≥2 prior therapies: 5-year follow-up of a pivotal Phase II study	#5352 poster presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III Monday 8 December 2025 6pm-8pm EST
	Fixed-duration subcutaneous mosunetuzumab continues to demonstrate high rates of durable responses in patients with relapsed/refractory follicular lymphoma after ≥2 prior therapies: 3-year follow-up from a pivotal Phase II study	#5353 poster presentation Session: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III Monday 8 December 2025

		6pm-8pm EST
Lunsumio / Columvi	Patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) preferred fixed-duration treatments with less frequent administrations in the era of novel bispecific antibodies (BsAbs)	#6179 poster presentation Session: 902. Health Services and Quality Improvement: Lymphoid Malignancies: Poster III Monday 8 December 2025 6pm-8pm EST
	Diverse preferences for treatment options in relapsed/refractory (R/R) follicular lymphoma (FL): Survey results from patients in the United States (US)	#6180 poster presentation Session: 902. Health Services and Quality Improvement: Lymphoid Malignancies: Poster III Monday 8 December 2025 6pm-8pm EST
	Differences in patient-reported time toxicity between bispecific antibody (BsAb) options: Impact of treatment duration and dosing frequency on patient-reported time burden in relapsed/refractory (R/R) follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL)	#6181 poster presentation Session: 902. Health Services and Quality Improvement: Lymphoid Malignancies: Poster III Monday 8 December 2025 6pm-8pm EST
NXT007	NXT007 prophylaxis in people with hemophilia A with or without FVIII inhibitors: a global phase I/II multiple-ascending-dose study	#302 oral presentation Session: 322. Hemophilia A and B: Clinical and Epidemiological: Prophylaxis Across the Age Spectrum Saturday 6 December 2025

		4:15pm EST
	Ex Vivo Evaluation of the Procoagulant Effect of NXT007 Prophylaxis in People with Hemophilia A without Factor VIII Inhibitors: Phase I/II Study (NXTAGE)	#3061 poster presentation Session: 322. Hemophilia A and B: Clinical and Epidemiological: Poster II Sunday 7 December 2025 6pm-8pm EST
	Pharmacodynamic biomarkers in people with hemophilia A receiving multiple ascending doses of NXT007	#4841 poster presentation Session: 322. Hemophilia A and B: Clinical and Epidemiological: Poster III Monday 8 December 2025 6pm-8pm EST
Polivy® (polatuzumab vedotin)	Transcriptional profiling refines DLBCL classification and identifies subtypes with distinct therapeutic vulnerabilities	#49 oral presentation Session: 621. Lymphomas: Translational – Molecular and Genetic - Subtyping strategies to unlock new therapeutic vulnerabilities Saturday 6 December 2025 9:30am EST
	Assessment of the prognostic value of FDG PET-derived markers and responses in POLARIX	#5329 poster presentation Session: 622. Lymphomas: Translational – Non-Genetic: Poster III Monday 8 December 2025 6pm-8pm EST
SPK-8011QQ	Preclinical evaluation of SPK-8011QQ, an adeno-associated virus gene therapy for	#1068 oral presentation

	people with hemophilia A leveraging the dirloctocogene samoparvovec platform encoding an activated protein C-resistant B-domain deleted factor VIII	Session: 801. Gene Therapies: Technological Developments in Gene Therapy Monday 8 December 2025 5:45pm EST
Venclexta®/ Venclyxto® (venetoclax)**	Long-term immune reconstitution and final 1-year follow-up after fixed-duration venetoclax-obinutuzumab (VenO) in first-line (1L) chronic lymphocytic leukemia (CLL): results from the Phase III CRISTALLO trial	#682 oral presentation Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Frontline Treatment Strategies for CLL Sunday 7 December 2025 5:15pm EST
	Results from PARADIGM - a phase 2 randomized study comparing venetoclax and azacitidine to conventional induction chemotherapy for newly diagnosed fit adults with acute myeloid leukemia	Plenary session Sunday 7 December 2025 2pm-4pm EST
	Fixed-duration versus continuous targeted treatment for previously untreated chronic lymphocytic leukemia: Results from the randomized CLL17 trial	Plenary session Sunday 7 December 2025 2pm-4pm EST

**Based on the STARGLO data, Columvi in combination with GemOx is approved in 49 countries for the treatment of R/R DLBCL including the EU, UK, Australia and Canada. On 2 July 2025, the US Food and Drug Administration issued a Complete Response Letter for the supplemental Biologics License Application for Columvi in combination with GemOx for this indication.*

***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 off-the-shelf allogeneic CAR-T 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

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] Kruse-Jarres R, et al. Evolution of joint health and physical activity in people with hemophilia A without factor VIII inhibitors switching to emicizumab prophylaxis: A second interim analysis of the BEYOND ABR study. To be presented at: ASH Annual Meeting; 2025 Dec 6-9; Orlando, FL, USA. Abstract #1285.

[2] Callaghan MU, Negrier C, Paz-Priel I, et al. Long-term outcomes with emicizumab prophylaxis for hemophilia A with or without FVIII inhibitors from the HAVEN 1-4 studies. Blood. 2021;137(16):2231-2242.

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[13] Kiialainen A, et al. Pharmacodynamic biomarkers in people with hemophilia A receiving multiple ascending doses of NXT007. To be presented at: ASH Annual Meeting; 2025 Dec 6-9; Orlando, FL, USA. Abstract #4841.

[14] Nogami K, et al. Ex Vivo Evaluation of the Procoagulant Effect of NXT007 Prophylaxis in People with Hemophilia A without Factor VIII Inhibitors: Phase I/II Study (NXTAGE). To be presented at: ASH Annual Meeting; 2025 Dec 6-9; Orlando, FL, USA. Abstract #3061.

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