Media & Investor Release

Roche to present data at ASH 2022 showcasing strength of haematology portfolio and expanding into new areas to address more patient needs

- **Interim data from phase III HAVEN 7 study reinforce Hemlibra's efficacy and safety in infants with severe haemophilia A without factor VIII inhibitors[1]**
- **New and updated data support use of Polivy in diffuse large B-cell lymphoma, including its potential as a treatment option for previously untreated patients[2]**
- **New and updated data for innovative CD20xCD3 T-cell engaging bispecific antibodies Lunsumio and glofitamab further enhance their potential as effective, off-the-shelf, fixed-duration treatment options for people with lymphoma[3,4,5,6,7]**
- **First phase III data for crovalimab show the co-primary efficacy endpoints were met, with subcutaneous injections achieving disease control in people with paroxysmal nocturnal haemoglobinuria as shown in COMMODORE 3 study in China[8]**

Basel, 3 November 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that it will present new data from its industry-leading haematology portfolio at the 64th American Society of Hematology (ASH) Annual Meeting from 10-13 December 2022. The data to be presented span numerous blood diseases, including haemophilia A, paroxysmal nocturnal haemoglobinuria (PNH), and various types of blood cancers, including non-Hodgkin lymphoma (NHL) and multiple myeloma. Roche's approved and investigational medicines will be featured in more than 50 abstracts, including more than 15 oral presentations.

"We continually strive to improve patient outcomes by exploring new treatment options across blood disorders, such as lymphomas and rare blood diseases, where unmet needs remain high," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "The data we are presenting reinforce our ongoing commitment to redefining treatment paradigms, improving on existing standards of care and addressing a diversity of patient and healthcare system needs."

Roche's continued commitment to reinforcing strength of current portfolio

With 25 years of expertise in blood diseases, Roche has developed new medicines that changed the standard of care in several blood disorders with high unmet need. The data at

this year's meeting exemplify Roche's commitment to investing in its current portfolio to further improve patient outcomes.

- Interim data from the phase III HAVEN 7 study reinforce the efficacy and safety of Hemlibra® (emicizumab) in infants with severe haemophilia A without factor VIII inhibitors.[1] For this population, early prophylaxis may prevent long-term damage to joints and muscles and potentially reduce the risk of intracranial haemorrhage, which can be life-threatening.[9]
- New data evaluating Polivy® (polatuzumab vedotin) that underscore the potential impact of this treatment for the diffuse large B-cell lymphoma (DLBCL) patient community will be shared at the meeting. Health-related quality of life (HRQoL) data from the phase III POLARIX study will be presented, highlighting the potential impact of Polivy in combination with MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) on reducing the need for subsequent treatments in people with previously untreated DLBCL, a population where multiple subsequent treatments can be a significant treatment burden.[2] Based on data from the POLARIX study, this Polivy combination has been approved in the EU and recently, Japan, for the treatment of adult patients with previously untreated DLBCL.
- Roche is presenting updated data from the broadest and most comprehensive CD20xCD3 bispecific antibody development programme in the industry. This aims to provide off-the-shelf, fixed-duration treatment options, which address the unique and diverse needs of people with blood cancers. Data include updated analyses for Lunsumio® (mosunetuzumab), the first CD20xCD3 T-cell engaging bispecific antibody approved by the European Commission to treat follicular lymphoma (FL), and glofitamab, for which data have been submitted for approval to the European Medicines Agency, and submissions to additional health authorities worldwide, including the U.S. Food and Drug Administration (FDA), are ongoing.
    - An updated analysis from the pivotal phase II GO29781 study of Lunsumio in people with relapsed or refractory (R/R) FL after two or more prior therapies will show continued durable responses across multiple key efficacy endpoints in addition to offering the potential to be administered in an outpatient setting.[3] In addition, studies evaluating Lunsumio as a monotherapy and in novel combinations for the treatment of DLBCL in earlier lines of treatment will be presented, highlighting the potential of Lunsumio in other settings.[4,5]
    - Updated results from the phase II NP30179 study will show a fixed course of glofitamab monotherapy can deliver durable complete responses in people with heavily pre-treated aggressive lymphomas.[6,7] Results from the pivotal R/R DLBCL cohort indicate patients can maintain durable responses following fixed-duration treatment with glofitamab, potentially allowing them to benefit from a treatment-free period.[6]

Exploring and innovating in new areas of unmet need

Roche is applying its scientific expertise to expand its haematology clinical development programme by exploring additional blood diseases and bringing innovations that address the various needs of patients in areas of high unmet need.

- The first phase III clinical data for crovalimab from the COMMODORE 3 study in China, will be presented at ASH. These data demonstrate that crovalimab met the co-primary efficacy endpoints, suggesting that crovalimab is efficacious and well-tolerated in people with PNH, a rare and life-threatening blood condition, where healthy red blood cells are targeted and destroyed by the body's complement system.[8] There are currently no effective treatment options for PNH broadly available in China.
- Spark Therapeutics, a member of the Roche Group, will share updated long-term follow-up data from the ongoing phase I/II clinical trial of SPK-8011, an investigational AAV-based gene therapy being developed for the treatment of haemophilia A.[10] The acquisition of Spark Therapeutics brought new capabilities in haemophilia A to address the high unmet medical need for people living with this disease and endeavour to create additional benefit beyond current treatment options.
- Positive data on cevostamab will be presented at ASH, including data from the phase I GO39775 study, which suggest that patients with heavily pre-treated multiple myeloma can maintain durable responses with fixed-duration cevostamab.[11] Additionally, phase I data from Roche's GPRC5DxCD3 T-cell engaging bispecific antibody, RG6234, showing encouraging preliminary activity in people with R/R multiple myeloma, will be presented.[12] With this pipeline, Roche is committed to advancing treatments for multiple myeloma, which remains an incurable disease characterised by multiple relapses.

Further information on the key abstracts featuring Roche medicines that will be presented at ASH can be found in the table below.

Follow Roche on Twitter via @Roche and on LinkedIn and keep up to date with ASH Annual Meeting news and updates by using the hashtag #ASH22.

Medicine	Abstract title	Abstract number/presentation details
Cevostamab	Pre-treatment with Tocilizumab Prior to the CD3 Bispecific Cevostamab in Patients with Relapsed/Refractory Multiple Myeloma (RRMM) Showed a Marked Reduction in Cytokine Release Syndrome Incidence and Severity	#567 poster presentation Session: 653 Sunday, 11 December 2022 12:00-13:30 CT/19:00-20:30 CET
	Enduring Responses After One-Year, Fixed-Duration Cevostamab Therapy in Patients with Relapsed/Refractory Multiple Myeloma: Early Experience from a Phase I Study	#1924 poster presentation Session: 653 Saturday, 10 December 2022 17:30-19:30 CT/00:30-2:30 CET [+1 day]
Crovalimab	Results From the First Phase 3 Crovalimab (C5-Inhibitor) Study (COMMODORE 3): Efficacy and Safety in Complement Inhibitor-Naive Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)	#293 oral presentation Session: 508 Saturday, 10 December 2022 16:00-17:30 CT/23:00-00:30 CET
	Pharmacokinetic Characterization and Exposure-Response Relationship of Crovalimab in the COMPOSER and COMMODORE 3 Trials of Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)	#1247 poster presentation Session: 508 Saturday, 10 December 2022 17:30-19:30 CT/00:30-02:30 CET [+1 day]
Glofitamab	Glofitamab Monotherapy Induces High Complete Response Rates in Patients with Heavily Pre-treated Relapsed or Refractory Mantle Cell Lymphoma	#74 oral presentation Session: 623 Saturday, 10 December 2022 09:30-11:00 CT/16:30-18:00 CET

	Relapse is Uncommon in Patients with Large B-Cell Lymphoma Who Are in Complete Remission at the End of Fixed-Course Glofitamab Treatment	#441 oral presentation Session: 626 Sunday, 11 December 2022 09:30-11:00 CT/16:30-18:00 CET
	Glofitamab Plus R-CHOP Induces High Response Rates and a Favorable Safety Profile in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL): Results from a Phase Ib Study	#737 oral presentation Session: 626 Monday, 12 December 2022 10:30-12:00 CT/19:00-20:30 CET
Hemlibra	Emicizumab Prophylaxis for the Treatment of Infants with Severe Hemophilia A without Factor VIII Inhibitors: Results from the Interim Analysis of the HAVEN 7 Study	#187 oral presentation Session: 322 Saturday, 10 December 2022 14:00-15:30 CT/21:00-22:30 CET
	Real-World Safety of Emicizumab: Interim Analysis of the European Haemophilia Safety Surveillance (EUHASS) Database	#192 oral presentation Session: 322 Saturday, 10 December 2022 14:00-15:30 CT/21:00-22:30 CET
	Characteristics and Bleeding Behavior of Females with Mild Hemophilia A: Longitudinal Study from PicnicHealth Hemophilia A Database	#27 oral presentation Session: 322 Saturday, 10 December 2022 09:30-11:00 CT/16:00-18:00 CET
	Emicizumab and Females with Hemophilia A: Case Series from ATHN 7	#1162 poster presentation Session: 322

		Saturday, 10 December 2022 17:30-19:30 CT/00:30-02:30 CET [+1 day]
	Characteristics and Healthcare Utilization of Patients with Mild or Moderate Hemophilia A in the US - An Analysis from the PicnicHealth Cohort	#1170 poster presentation Session: 322 Saturday, 10 December 2022 17:30-19:30 CT/00:30-02:30 CET [+1 day]
Lunsumio	Mosunetuzumab Monotherapy Demonstrates Durable Efficacy with a Manageable Safety Profile in Patients with Relapsed/Refractory Follicular Lymphoma who have Received ≥2 Prior Therapies: Updated Results from a Pivotal Phase II Study	#610 oral presentation Session: 623 Sunday, 11 December 2022 16:30-18:00 CT/23:30-01:00 CET
	Mosunetuzumab Monotherapy Continues to Demonstrate Promising Efficacy and Durable Complete Responses in Elderly/Unfit Patients with Previously Untreated Diffuse Large B-cell Lymphoma	#738 oral presentation Session: 626 Monday, 12 December 2022 10:30-12:00 CT/17:30-19:00 CET
	Mosunetuzumab with Polatuzumab Vedotin is Effective and has a Manageable Safety Profile in Patients Aged <65 and ≥65 Years with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) and ≥1 Prior Therapy: Subgroup Analysis of a Phase Ib/II Study	#1630 poster presentation Session: 626 Saturday, 10 December 2022 17:30-19:30 CT/00:30-02:30 CET [+1 day]
	SUNMO: A Phase III Trial Evaluating the Efficacy and Safety of Mosunetuzumab in Combination with Polatuzumab Vedotin versus Rituximab in Combination with Gemcitabine plus Oxaliplatin in Patients with Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma	#1637 poster presentation Session: 626 Saturday, 10 December 2022 17:30-19:30 CT/00:30-02:30 CET [+1 day]

	Subcutaneous (SC) Mosunetuzumab is Active with a Manageable Safety Profile in Patients with Relapsed/Refractory (R/R) B-cell non-Hodgkin Lymphoma (B-NHL): Updated Results from a Phase I/II Study	#1628 poster presentation Session: 626 Saturday, 10 December 2022 17:30-19:30 CT/00:30-02:30 CET [+1 day]
Polivy	Risk Profiling of Patients with Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL) by Measuring Circulating Tumor DNA (ctDNA): Results from the POLARIX Study	#542 oral presentation Session: 621 Sunday, 11 December 2022 12:00-13:30 CT/19:00-20:30 CET
	Polatuzumab Vedotin plus Bendamustine and Rituximab in Relapsed/Refractory Diffuse Large B-cell Lymphoma (R/R DLBCL): Final Results of a Phase Ib/II Randomized Study and Single-Arm Extension (Ext) Study	#4260 poster presentation Session: 626 Monday, 12 December 2022 18:00-20:00 CT/01:00-03:00 CET [+1 day]
	Total Cost of Care in Relapsed/Refractory (R/R) Diffuse Large B-cell Lymphoma (DLBCL)	#3527 poster presentation Session: 902 Sunday, 11 December 2022 18:00-20:00 CT/01:00-03:00 CET [+1 day]
	Health-Related Quality of Life (HRQoL) in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Treated with Polatuzumab Vedotin, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone (Pola-R-CHP) versus Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (R-CHOP) in the Phase III POLARIX Study	#2949 poster presentation Session: 626 Sunday, 11 December 2022 18:00-20:00 CT/01:00-03:00 CET [+1 day]
RG6234	RG6234, a GPRC5DxCD3 T-cell Engaging Bispecific Antibody, is Highly Active in Patients (pts) with Relapsed/Refractory Multiple Myeloma	#161 oral presentation Session: 653

	(RRMM): Updated Intravenous (IV) and First Subcutaneous (SC) Results from a Phase I Dose-Escalation study	Saturday, 10 December 2022 12:00-13:30 CT/19:00-20:30 CET
SPK-8011	Long-Term Durable FVIII Expression with Improvements in Bleeding Rates Following AAV-Mediated FVIII Gene Transfer for Hemophilia A: Multiyear Follow-up on the Phase I/II Trial of SPK-8011	#783 oral presentation Session: 801 Monday, 12 December 2022 10:30-12:00 CT/17:30-19:00 CET
	Rapid Clearance of Vector Following AAV-Mediated FVIII Gene Transfer in the Phase I/II Trial of SPK-8011 in People with Hemophilia A	#4783 poster presentation Session: 801 Monday, 12 December 2022 18:00-20:00 CT/01:00-03:00 CET [+1 day]
	The Effects of Immunomodulation with Corticosteroids to Manage an AAV Capsid Immune response in the Phase I/II Study of SPK-8011	#4779 poster presentation Session: 801 Monday, 12 December 2022 18:00-20:00 CT/01:00-03:00 CET [+1 day]

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) and Lunsumio® (mosunetuzumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies glofitamab, targeting both CD20 and CD3 and cevostamab, targeting both FcRH5 and CD3, Tecentriq® (atezolizumab), a monoclonal antibody designed to bind with PD-L1, 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 and Spark Therapeutics gene therapy research in haemophilia A

We believe gene therapy has the potential to revolutionise medicine and improve the lives of patients with genetic and other serious diseases. Pairing Roche's long-standing commitment to developing medicines in haemophilia with Spark Therapeutics' proven gene therapy expertise brings together the best team of collaborators researching gene therapies in haemophilia A.

It is our aligned objective to develop gene therapies for haemophilia A that, with the lowest effective dose and the optimal immunomodulatory regimen, demonstrate safety, predictability, efficacy, and durability for patients.

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 endeavor 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

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[2] Friedberg JW, et al. Health-Related Quality of Life (HRQoL) in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Treated with Polatuzumab Vedotin, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone (Pola-RCHP) versus Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (R-CHOP) in the Phase III POLARIX Study. Presentation at: ASH Annual Meeting and Exposition; 2022 Dec 10-13 Abstract #2949.
[3] Bartlett NL, et al. Mosunetuzumab Monotherapy Demonstrates Durable Efficacy with a Manageable Safety Profile in Patients with Relapsed/Refractory Follicular Lymphoma Who Received ≥2 Prior Therapies: Updated Results from a Pivotal Phase II Study. Presentation at: ASH Annual Meeting and Exposition; 2022 Dec 10-13 Abstract #610.
[4] Olszewski AJ, et al. Mosunetuzumab Monotherapy Continues to Demonstrate Promising Efficacy and Durable Complete Responses in Elderly/Unfit Patients with Previously Untreated Diffuse Large B-cell Lymphoma. Presentation at: ASH Annual Meeting and Exposition; 2022 Dec 10-13 Abstract #738.
[5] Olszewski AJ, et al. Mosunetuzumab with Polatuzumab Vedotin is Effective and has a Manageable Safety Profile in Patients Aged <65 and ≥65 Years with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) and ≥1 Prior Therapy: Subgroup Analysis of a Phase Ib/II Study. Presentation at: ASH Annual Meeting and Exposition; 2022 Dec 10-13 Abstract #1630.
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[11] Lesokhin A, et al. Enduring Responses After 1-Year, Fixed-Duration Cevostamab Therapy in Patients with Relapsed/Refractory Multiple Myeloma: Early Experience from a Phase I Study. Presentation at: ASH Annual Meeting and Exposition; 2022 Dec 10-13 Abstract #1924.
[12] Carlo-Stella C, et al. RG6234, a GPRC5DxCD3 T-cell engaging bispecific antibody, is highly active in patients (pts) with relapsed/refractory multiple myeloma (RRMM): updated intravenous (IV) and first subcutaneous (SC) results from a Phase I dose-escalation study. Presentation at: ASH Annual Meeting and Exposition; 2022 Dec 10-13 Abstract #161.

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