Roche to present new data across 16 blood disorders at the American Society of Hematology 2020 Annual Meeting

- **New data for Roche's CD20xCD3 bispecific antibodies will be featured, as well as first clinical data on cevostamab, a first-of-its-kind FcRH5xCD3 bispecific antibody, in multiple myeloma**
- **Longer-term data for Roche's approved therapies in haemophilia A, chronic lymphocytic leukaemia and diffuse large B-cell lymphoma, reinforce the favourable efficacy and safety profile of each medicine**
- **Eleven Roche medicines will be featured in more than 80 abstracts, including 22 oral presentations**

Basel, 5 November 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data for its approved and investigational medicines will be presented at the all-virtual 62nd American Society of Hematology (ASH) Annual Meeting and Exposition from 5 – 8 December 2020. Eleven Roche medicines will be featured in more than 80 abstracts, including 22 oral presentations. With studies spanning 16 blood disorders, including non-Hodgkin lymphoma (NHL), leukaemia, multiple myeloma (MM) and haemophilia A, these data highlight the strength and breadth of Roche's haematology portfolio and pipeline, and commitment to developing innovative treatment solutions for patients in need.

"We have one of the largest clinical development programmes in malignant and non-malignant haematology and we continuously seek to improve patient outcomes by exploring new therapeutic mechanisms, combinations and clinical trial endpoints," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Our data reflect our ongoing commitment to following the science and improving the lives of patients with some of the most difficult-to-treat blood disorders."

Building on its 20-year legacy in antibody engineering, Roche is exploring novel mechanisms of action for immunotherapies including T-cell engaging bispecific antibodies. Data on three investigational bispecifics will be presented, including:

- Progress from Roche's CD20xCD3 bispecific antibody development programmes, including updated results for mosunetuzumab in relapsed or refractory (R/R) follicular lymphoma and early data in first-line diffuse large B-cell lymphoma (DLBCL). Additionally, data demonstrating high response rates with step-up dosing of glofitamab in people with R/R NHL will be presented.
- First clinical safety, efficacy and biomarker data from cevostamab (BFCR4350A), a first-of-its-kind FcRH5xCD3 bispecific antibody targeting FcRH5 on myeloma cells and CD3 on T-cells, will be presented, with initial results from the ongoing phase I GO39775 dose-escalation study in people with heavily pre-treated R/R MM.

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Roche will also be sharing longer-term data, including results on novel clinical trial endpoints, that support the known efficacy and safety of its established medicines, including:

- Three year follow-up data from the pivotal phase III HAVEN study programme (HAVEN 1-4 studies), reinforcing the efficacy and safety profile of Hemlibra® (emicizumab) in people with haemophilia A with and without factor VIII inhibitors.
- Results from the first interim analysis of the European Haemophilia Safety Surveillance database, examining real-world data to monitor the ongoing safety of Hemlibra in people with haemophilia A with and without factor VIII inhibitors.
- Results on fixed-duration, chemotherapy-free combinations in chronic lymphocytic leukaemia (CLL), including five-year analysis of the phase III MURANO study, investigating Venclexta®/Venclyxto® (venetoclax) plus MabThera®/Rituxan® (rituximab) in R/R CLL, with updates on minimal residual disease and long-term outcomes analysis. Venclexta/Venclyxto is being developed by AbbVie and Roche.
- Updated results from the phase Ib/II randomised GO29365 study of fixed-duration Polivy® (polatuzumab vedotin), plus bendamustine and MabThera/Rituxan, in people with R/R DLBCL, including preliminary results from a single-arm extension cohort of 106 additional patients.

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 keep up to date with ASH Annual Meeting news and updates by using the hashtag #ASH20.

Medicine	Abstract title	Abstract number/presentation details
Mosunetuzumab (investigational)	Mosunetuzumab Shows Promising Efficacy in Patients with Multiply Relapsed Follicular Lymphoma: Updated Clinical Experience from a Phase I Dose-Escalation Trial	*#702 oral presentation* *Session: 623* *Monday 7 December 2020* *13:30-15.00 PT (presentation time 14.00 PT)*
	Single-agent Mosunetuzumab is a Promising Safe and Efficacious Chemotherapy-Free Regimen for Elderly/Unfit Patients with Previously Untreated Diffuse Large B-Cell Lymphoma	*#401 oral presentation* *Session: 626* *Sunday 6 December 2020* *12:00-13:30 PT (presentation time 12:15 PT)*
	Mosunetuzumab, a Novel CD20/CD3 Bispecific Antibody, in Combination With CHOP Confers High Response Rates in	*#1184 poster presentation* *Session: 626* *Saturday 5 December 2020* *07:00-15:30 PT*

	Patients with Diffuse Large B-Cell Lymphoma	
Glofitamab (investigational)	Glofitamab Step-Up Dosing Induces High Response Rates in Patients with Hard-to-Treat Refractory or Relapsed Non-Hodgkin Lymphoma	*#403 oral presentation* *Session: 626* *Sunday 6 December 2020* *12:00-13:30 PT (presentation time 12.45 PT)*
Cevostamab (BFCR4350A; a FcRH5xCD3 bispecific antibody) (investigational)	Initial Clinical Activity and Safety of BFCR4350A, a FcRH5/CD3 T-Cell-Engaging Bispecific Antibody, in Relapsed/Refractory Multiple Myeloma	*#292 oral presentation* *Session: 653* *Saturday 5 December 2020* *14:00-15.30 PT (presentation time 14.30 PT)*
	Early Pharmacodynamic Changes in T-Cell Activation, Proliferation, and Cytokine Production Confirm the Mode of Action of BFCR4350A, a FcRH5/CD3 T-Cell-Engaging Bispecific Antibody, in Patients with Relapsed/Refractory Multiple Myeloma	*#3213 poster presentation* *Session: 653* *Monday 7 December 2020* *07:00-15.30 PT*
Hemlibra (approved use)	Safety and Efficacy of Emicizumab in Persons with Hemophilia A With or Without FVIII Inhibitors: Pooled Data from Four Phase III Studies (HAVEN 1-4)	*#1800 poster presentation* *Session: 322* *Sunday 6 December 2020* *07:00-15:30 PT*
	Real-World Safety of Emicizumab: The First Interim Analysis of the European Haemophilia Safety Surveillance (EUHASS) Database	*#2685 poster presentation* *Session: 322* *Monday 7 December 2020* *07:00-15:30 PT*
Venclexta/Venclyxto (approved use)	Five-Year Analysis of MURANO Study Demonstrates Enduring Undetectable Minimal Residual Disease (uMRD) in a Subset of Relapsed/Refractory Chronic Lymphocytic Leukemia (R/R	*#125 oral presentation* *Session: 642* *Saturday 5 December 2020* *09:30-11:00 PT (presentation time 10:00 PT)*

	CLL) Patients (Pts) Following Fixed-Duration Venetoclax-Rituximab (VenR) Therapy (Tx)	
	Clonal Dynamics after Venetoclax-Obinutuzumab Therapy: Novel Insights from the Randomized, Phase 3 CLL14 trial	*#127 oral presentation* *Session: 642* *Saturday 5 December 2020* *09:30-11:00 PT (presentation time 10:30 PT)*
	Results of Venetoclax and Azacitidine Combination in Chemotherapy Ineligible Untreated Patients with Acute Myeloid Leukemia with FLT3 mutations	*#1904 poster presentation* *Session: 613* *Sunday 6 December 2020* *07:00-15:30 PT*
	Results of Venetoclax and Azacitidine Combination in Chemotherapy Ineligible Untreated Patients with Acute Myeloid Leukemia with IDH 1/2 Mutations	*#461 oral presentation* *Session: 613* *Sunday 6 December 2020* *14:00-15:30 PT (presentation time 14:45 PT)*
	Characteristics and Outcome of Patients with Chronic Lymphocytic Leukaemia and Partial Response to Venetoclax-Obinutuzumab	*#1310 poster presentation* *Session: 642* *Saturday 5 December 2020* *07:00-15:30 PT*
Polivy (approved use)	Polatuzumab Vedotin Plus Bendamustine and Rituximab in Relapsed/Refractory Diffuse Large B-Cell Lymphoma: Updated Results of a Phase Ib/II Randomized Study and Preliminary Results of a Single-Arm Extension	*#3020 poster presentation* *Session: 626* *Monday 7 December 2020* *07:00-15:30 PT*
	Risk Profiling of Relapsed/Refractory Diffuse Large B-Cell Lymphoma Patients By Measuring Circulating Tumor DNA	*#532 oral presentation* *Session: 627* *Monday 7 December 2020* *07:00-08:30 PT (presentation time 07:30 PT)*

About Roche in haematology
Roche has been developing medicines for people with malignant and non-malignant blood diseases for over 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, and Hemlibra® (emicizumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies, glofitamab and mosunetuzumab, targeting both CD20 and CD3, and cevostamab, targeting FcRH5 on myeloma cells and CD3 on T-cells; 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
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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.

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