Media Release

Roche to present new data from its industry-leading haematology portfolio at the American Society of Hematology 2018 Annual Meeting

- **Ten medicines featured in over 70 abstracts, including 25 oral presentations**
- **Additional data from three pivotal studies of Hemlibra in people with haemophilia A, with or without factor VIII inhibitors**
- **Updated data from three pivotal studies of Venclexta/Venclyxto in chronic lymphocytic leukaemia and acute myeloid leukaemia**
- **First clinical data for two novel T-cell engaging bispecific antibodies in non-Hodgkin lymphoma**

Basel, 1 November 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data for its approved and investigational medicines across a range of blood diseases, and including several first-in-class medicines, will be presented at the 60th American Society of Hematology (ASH) Annual Meeting from 1-4 December, 2018. Ten Roche medicines will be featured in more than 70 abstracts, including 25 oral presentations, across 15 blood diseases.

"We look forward to sharing progress from our broad development programme in haematology at ASH this year, reflecting our approach to understand mechanisms of blood diseases at the molecular level," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are excited to be presenting data across multiple blood diseases, including studies of several first-in-class medicines with the potential to transform standards of care and improve patients' lives."

Hemlibra® (emicizumab), which represents the first new class of medicine in nearly 20 years for people with haemophilia A, will be featured in 12 abstracts at the congress. New data in children younger than 12 with haemophilia A with and without factor VIII inhibitors will be presented, including the full results from the pivotal HAVEN 2 study evaluating three different Hemlibra dosing options (once weekly, every two weeks or every four weeks) in children with haemophilia A with factor VIII inhibitors. Additionally, treatment preference data from the pivotal HAVEN 3 study in people with haemophilia A without factor VIII inhibitors and the pivotal HAVEN 4 study in people with haemophilia A with and without factor VIII inhibitors will be presented. Hemlibra was recently approved by the US Food and Drug Administration (FDA) for the treatment of haemophilia A without factor VIII inhibitors and is the only haemophilia treatment that can be administered subcutaneously and at multiple dosing options for all people with haemophilia A, with and without factor VIII inhibitors.

Roche will also share data for medicines for a range of blood cancers, across multiple lines of treatment. Highlights include updated results from the phase III MURANO study evaluating

Venclexta®/Venclyxto® (venetoclax) in chronic lymphocytic leukaemia (CLL). In addition, data evaluating Venclexta/Venclyxto in acute myeloid leukaemia (AML) will be featured, including two phase Ib/II combination studies (M14-358 study and M14-387 study). Venclexta/Venclyxto was recently approved in Europe and the United States as a treatment for relapsed or refractory CLL, and is currently under review by the FDA for the treatment of previously untreated AML in combination with a hypomethylating agent or in combination with low dose cytarabine, with a decision expected by end of year. Venclexta/Venclyxto is being developed by AbbVie and Roche.

Updated efficacy data from the phase II GO29365 study evaluating polatuzumab vedotin, an investigational anti-CD79b antibody drug conjugate, in combination with MabThera®/Rituxan® (rituximab) plus bendamustine, in relapsed or refractory diffuse large B-cell lymphoma (DLBCL), will also be presented. The results of the DLBCL portion of the GO29365 study will be submitted to health authorities around the world for approval consideration. Data from the phase III GALLIUM study of Gazyva®/Gazyvaro® (obinutuzumab) in previously untreated follicular lymphoma which support the prognostic value of minimal residual disease status at the end of induction treatment will also be presented.

Finally, Roche will present early data for two novel T-cell engaging bispecific antibodies in non-Hodgkin lymphoma (NHL), which includes initial efficacy and safety results from the first clinical trials for the investigational medicines mosunetuzumab and CD20-TCB. These bispecific antibodies redirect T-cells to engage and eliminate malignant B-cells. This builds on Roche's extensive history and expertise in the development of anti-CD20 antibodies for the treatment of numerous B-cell malignancies.

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 #ASH18.

Medicine	Abstract title	Abstract number/Presentation details
Hemlibra (approved use; updated study results)	Emicizumab Prophylaxis Provides Flexible and Effective Bleed Control in Children with Hemophilia A with Inhibitors: Results from the HAVEN 2 Study	#632 *Oral presentation* *(session 322)* *Monday 3 December 2018* *10.45 PT*
	Immunogenicity of Emicizumab in People with Hemophilia A (PwHA): Results from the HAVEN 1–4 Studies	#633 *Oral presentation* *(session 322)* *Monday 3 December 2018* *11.00 PT*
	Preference for Emicizumab Over Prior Factor Treatments: Results From the HAVEN 3 and HAVEN 4 Studies	#1187 *Poster presentation* *(session 322)* *Saturday 1 December 2018* *18.15 – 20.15 PT*
	Every 2 Weeks or Every 4 Weeks Subcutaneous Injection of Emicizumab in Pediatric Patients with Severe Hemophilia A without Inhibitors: A Multi-Center, Open-Label Study in Japan (HOHOEMI Study)	#1186 *Poster presentation* *(session 322)* *Saturday 1 December 2018* *18.15 – 20.15 PT*
Venclexta/Venclyxto (approved use; updated study results)	First Prospective Data on Impact of Minimal Residual Disease on Long-term Clinical Outcomes after Venetoclax plus Rituximab versus Bendamustine plus Rituximab: Phase III MURANO Study	#695 *Oral presentation* *(session 642)* *Monday 3 December 2018* *11.30 PT*
	MURANO trial establishes feasibility of time-limited venetoclax-rituximab (VenR) combination therapy in relapsed/refractory (R/R) Chronic Lymphocytic Leukemia (CLL)	#184 *Oral presentation* *(session 642)* *Saturday 1 December 2018* *14.45 PT*
(investigational use)	Venetoclax in combination with hypomethylating agents induces rapid, deep, and durable responses in patients with AML ineligible for intensive therapy	#285 *Oral presentation* *(session 615)* *Sunday 2 December 2018* *08.00 PT*

Medicine	Abstract title	Abstract number/Presentation details
Venclexta/Venclyxto (investigational use)	Venetoclax with low-dose cytarabine induces rapid, deep, and durable responses in previously untreated older adults with AML ineligible for intensive chemotherapy	#284 *Oral presentation (session 615) Sunday 2 December 2018 07.45 PT*
Polatuzumab vedotin (investigational)	Polatuzumab Vedotin (Pola) Plus Bendamustine (B) with Rituximab (R) or Obinutuzumab (G) in Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL): Updated Results of a Phase (Ph) Ib/II Study	#1683 *Poster presentation (session 626) Saturday 1 December 2018 18.15 – 20.15 PT*
Gazyva/Gazyvaro (approved use)	Minimal Residual Disease Response at End of Induction and During Maintenance Correlates with Updated Outcome in the Phase III GALLIUM Study of Obinutuzumab- or Rituximab-Based Immunochemotherapy in Previously Untreated Follicular Lymphoma Patients	#396 *Oral presentation (session 623) Sunday 2 December 2018 13.15 PT*
Mosunetuzumab (investigational)	Mosunetuzumab, a Full-Length Bispecific CD20/CD3 Antibody, Displays Clinical Activity in Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (NHL): Interim Safety and Efficacy Results from a Phase 1 Study	#399 *Oral presentation (session 626) Sunday 2 December 2018 12.30 PT*
CD20-TCB (investigational)	CD20-Tcb (RG6026), a Novel "2:1" Format T-Cell-Engaging Bispecific Antibody, Induces Complete Remissions in Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma: Preliminary Results from a Phase I First in Human Trial	#226 *Oral presentation (session 626) Saturday 1 December 2018 16.45 PT*

About Roche in haematology
For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. Today, we are investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. In addition to approved medicines MabThera®//Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), and Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, Roche's pipeline of investigational haematology medicines includes Tecentriq® (atezolizumab), an anti-CD79b antibody drug conjugate (polatuzumab vedotin/RG7596) and a small molecule which inhibits the interaction of MDM2 with p53 (idasanutlin/RG7388). Roche's dedication to developing novel molecules in haematology expands beyond malignancy, with the development of Hemlibra® (emicizumab), a bispecific monoclonal antibody for the treatment of haemophilia A.

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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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