Media Release

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Roche to present new data across a range of blood diseases at the American Society of Hematology (ASH) 2017 Annual Meeting

- **Further results from emicizumab phase III studies in people with haemophilia A with inhibitors will be featured**
- **New data for polatuzumab vedotin in a difficult-to-treat blood cancer, which led to FDA Breakthrough Therapy and EMA PRIME Designations, also to be presented**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data on its approved and investigational medicines for blood diseases will be presented at the 59th American Society of Hematology (ASH) Annual Meeting from 9 – 12 December, in Atlanta. Ten Roche medicines will be featured in over 75 abstracts, including 26 oral presentations, across eight blood diseases.

"At ASH this year, we look forward to presenting a wealth of data highlighting potential advances across the spectrum of blood diseases, from rare conditions like haemophilia A to common blood cancers like lymphoma," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "Our ongoing development programme in haematology is one of the largest in this area, underscoring our commitment to developing practice-changing medicines and improving outcomes for people with diseases of the blood."

Among Roche's clinical data to be featured at ASH are results from the ongoing trials for the investigational medicine emicizumab. Updated data with an additional six months of follow-up from the phase III HAVEN 1 and HAVEN 2 studies evaluating the safety and efficacy of emicizumab in adults, adolescents and children with haemophilia A with inhibitors will be presented. The HAVEN 2 study will be highlighted as part of ASH's official press program on 9 December at 07:30am EST. Additional results from the emicizumab clinical development programme will be presented during the meeting, including preliminary data from the phase III HAVEN 4 study exploring emicizumab prophylaxis administered every four weeks in people with haemophilia A with and without inhibitors, as well as real-world data from a non-interventional study in children under 12 years of age with haemophilia A with inhibitors.

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Roche will also be sharing data for medicines in late-stage development for a range of blood cancers. Highlights include results from a randomised phase II study evaluating polatuzumab vedotin, an investigational anti-CD79b antibody drug conjugate, in combination with MabThera®/Rituxan® (rituximab) and bendamustine versus MabThera/Rituxan and bendamustine for the treatment of people with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Based on data from this study, polatuzumab vedotin was recently granted Breakthrough Therapy Designation by the US Food and Drug Administration (FDA) and had previously received the PRIME (PRIority MEdicines) designation in Europe.

Additionally, results from studies of Gazyva®/Gazyvaro® (obinutuzumab), including new data from the phase III GALLIUM study in previously untreated follicular lymphoma, and data from the phase III PrefMab study evaluating patient preference for the subcutaneous (SC) formulation of MabThera/Rituxan Hycela™ (rituximab/rituximab and hyaluronidase human) as a treatment for DLBCL and follicular lymphoma will also be shared. Finally, results from multiple studies assessing the safety and efficacy of Venclexta™/Venclyxto™ (venetoclax) across chronic lymphocytic leukaemia (CLL), multiple myeloma (MM) and acute myeloid leukaemia (AML) will be presented. Venclexta/Venclyxto is being developed by AbbVie and Roche.
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 #ASH17.

Overview of key presentations featuring Roche medicines at ASH 2017

Medicine	**Abstract title**	**Abstract number/Presentation details**
Emicizumab (investigational)	Emicizumab Prophylaxis in Adolescent/Adult Patients with Hemophilia A Previously Receiving Episodic or Prophylactic Bypassing Agent Treatment: Updated Analyses from the HAVEN 1 Study	*#1071 Poster (session 322) Saturday 09 December 2017 5.30 – 7.30pm EST*
	HAVEN 2 Updated Analysis: Multicenter, Open-Label, Phase 3 Study to Evaluate Efficacy, Safety and Pharmacokinetics of Subcutaneous Administration of Emicizumab Prophylaxis in Pediatric Patients with Hemophilia A with Inhibitors	*#85 Oral presentation (session 322) Saturday 09 December 2017 9.45am EST (9.30 – 11.00am EST)*
	Emicizumab Subcutaneous Dosing Every 4 Weeks for the Management of Hemophilia A: Preliminary Data from the Pharmacokinetic Run-In Cohort of a Multicenter, Open-Label, Phase 3 Study (HAVEN 4)	*#86 Oral presentation (session 322) Saturday 09 December 2017 10.00am EST (9.30 – 11.00am EST)*
	Bleeding Events and Safety Outcomes in Pediatric Persons with Hemophilia A with Inhibitors: The First Non-interventional Study (NIS) from a Real-World Setting	*#1089 Poster (session 322) Saturday 09 December 2017 5.30 – 7.30pm EST*
Polatuzumab vedotin (investigational)	Addition of Polatuzumab Vedotin to Bendamustine and Rituximab (BR) Improves Outcomes in Transplant-Ineligible Patients with Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) Versus BR Alone: Results from a Randomized Phase 2 Study	*#2821 Poster (session 626) Sunday 10 December 2017 6.00 – 8.00pm EST*
Gazyva/Gazyvaro (approved use; updated study results)	Influence of Baseline Disease characteristics and Exposure to Obinutuzumab on Clinical Outcome in Patients with Previously Untreated Advanced Follicular Lymphoma Treated with Obinutuzumab-based Immunochemotherapy in the GALLIUM Trial	*#3848 Poster (session 605) Monday 11 December 2017 6.00 – 8.00pm EST*
	Early Disease Progression Predicts Poorer Survival in Patients with Follicular Lymphoma (FL) in the GALLIUM Study	*#1490 Poster (session 623) Saturday 09 December 2017 5.30 – 7.30pm EST*

MabThera SC /Rituxan Hycela (approved use; updated study results)	Efficacy and Safety of Subcutaneous or Intravenous Administration of Rituximab in Patients with CD20+ Diffuse Large B-Cell Lymphoma or Follicular Lymphoma: Final Results of the Randomized, Open-Label, Crossover, PrefMab Study	*#2834 Poster (session 626) Sunday 10 December 2017 6.00 – 8.00pm EST*
Venclexta/Venclyxto (investigational use)	Preliminary Safety and Efficacy of a Combination of Venetoclax and Obinutuzumab in Patients with Previously Untreated Chronic Lymphocytic Leukemia – Updated Results from a Phase 1b Study (GP28331)	*#430 Oral presentation (session 642) Sunday 10 December 2017 12.45pm EST (12.00 – 1:30pm EST)*
	Preliminary Results from a Phase Ib/II Study Evaluating Venetoclax in Combination with Cobimetinib or Idasanutlin in Patients with Relapsed or Refractory (R/R) AML	*#813 Oral presentation (session 616) Monday 11 December 2017 5.00pm EST (4:30 – 6:00pm EST)*
	Updated Safety and Efficacy of Venetoclax with Decitabine or Azacitidine in Treatment-Naive, Elderly Patients With Acute Myeloid Leukemia	*#2628 Poster(session 616) Sunday 10 December 2017 6.00 – 8.00pm EST*
	Phase 1/2 Study of Venetoclax with Low-Dose Cytarabine in Treatment-Naive, Elderly Patients with Acute Myeloid Leukemia Unfit for Standard Induction Therapy: Long-Term Outcomes	*#890 Oral presentation (session 616) Monday 11 December 2017 6.30pm EST (6:15 – 7:45pm EST)*

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 antagonist of MDM2 (idasanutlin/RG7388). Roche's dedication to developing novel molecules in haematology expands beyond malignancy, with the development of the investigational haemophilia A treatment emicizumab.

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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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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