Media Release

Roche to present new data highlighting breadth of haematology portfolio and pipeline at the American Society of Hematology 2019 Annual Meeting

- **Ten Roche medicines will be featured in more than 70 abstracts and 21 oral presentations, across a range of 15 blood cancers and non-malignant haematological conditions**
- **New data for CD20-CD3 bispecific cancer immunotherapies confirms their potential in difficult-to-treat lymphomas**
- **Long-term data and novel secondary endpoint analysis on Venclexta/Venclyxto combinations in certain blood cancers**
- **New analyses support Roche's portfolio for rare non-malignant blood conditions, including Hemlibra in haemophilia A and crovalimab in paroxysmal nocturnal haemoglobinuria**

Basel, 6 November 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data for its approved and investigational medicines across a range of blood diseases will be presented at the 61st American Society of Hematology (ASH) Annual Meeting from 7 – 10 December, 2019 in Orlando, Florida, US. Ten Roche medicines will be featured in more than 70 abstracts and 21 oral presentations. These data feature results in 15 blood diseases across numerous molecular targets and combinations, as well as different clinical endpoints that Roche is exploring.

"We are proud to present a broad range of data at ASH this year, and of the progress and commitment these data represent," said Levi Garraway, Roche's Chief Medical Officer and Head of Global Product Development. "We believe that our science-driven approach to therapeutic development will continue to provide new options for people with aggressive blood cancers and rare blood diseases."

Key data presentations in non-Hodgkin lymphoma (NHL)
Roche will present data for two CD20-CD3 T-cell engaging bispecific antibodies in NHL (mosunetuzumab and CD20-TCB), including a Plenary Session discussing the phase I/Ib GO29781 study results of mosunetuzumab in people with poor prognosis NHL, which includes those who have had prior chimeric antigen receptor T-cell therapy. The Plenary Session highlights the top six abstracts submitted to the meeting, as determined by the ASH Program Committee. Additionally, Roche will present new preliminary data evaluating CD20-TCB in combination with other Roche medicines.

Follow-up data on the pivotal phase Ib/II GO29365 study, investigating Polivy® (polatuzumab vedotin), a first-in-class antibody drug conjugate, in combination with MabThera®/Rituxan® (rituximab) and bendamustine in people with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) will also be presented. This study was the basis of Polivy's accelerated approval by the US Food and Drug Administration in June 2019 for people with R/R DLBCL who have received at least two prior therapies, and has been submitted to other health authorities around the world for approval consideration.

Key data presentations in chronic lymphocytic leukaemia (CLL), acute myeloid leukaemia (AML) and myelodysplastic syndromes (MDS)

Additionally, Roche will be sharing results from three studies of Venclexta®/Venclyxto® (venetoclax) representing chemotherapy-free treatment options for certain people with leukaemia. Further long-term follow-up data from the pivotal phase III MURANO study in CLL will be presented, as well as an updated analysis from the pivotal phase III CLL14 study with progression-free survival as the primary endpoint and minimal residual disease as a secondary endpoint, confirming the potential of Venclexta/Venclyxto as a fixed-duration treatment option. Results of the investigational medicine idasanutlin, an oral MDM2 inhibitor, in combination with Venclexta/Venclyxto in elderly patients with R/R AML will be shared. Additionally, new data will be presented for Venclexta/Venclyxto as a first-line treatment in MDS, a rare form of blood cancer that affects the bone marrow. Venclexta/Venclyxto is being developed by AbbVie and Roche.

Key data presentations in rare non-malignant blood conditions
Finally, data for rare blood conditions, including haemophilia A and paroxysmal nocturnal haemoglobinuria (PNH) will be presented. New analyses from the phase III HAVEN 3 study of Hemlibra® (emicizumab) in people with haemophilia A without factor VIII inhibitors will be presented. The analyses include data on the positive effect of Hemlibra on joint health, as well as additional data on the use of on-demand factor VIII replacement therapy to treat breakthrough bleeding in people receiving Hemlibra prophylaxis in the HAVEN 3 study compared to factor VIII prophylaxis in a non-interventional study. Roche is also sharing phase I/II data from the COMPOSER study, which assessed the investigational medicine crovalimab in people with PNH, a life-threatening disease where red blood cells are destroyed by the body's immune system. Crovalimab, a novel humanised anti-C5 monoclonal antibody designed to block the complement system, which plays a key role in PNH, was created by Chugai Pharmaceutical Co., Ltd. and is being co-developed by Roche.

Key abstracts featuring Roche medicines that will be presented at ASH can be found in the table below.

Medicine	Abstract title	Abstract number/presentation details
Mosunetuzumab (investigational)	Mosunetuzumab Induces Complete Remissions in Poor Prognosis Non-Hodgkin Lymphoma Patients, Including Those Who Are Resistant to or Relapsing After Chimeric Antigen Receptor T-Cell (CAR-T) Therapies, and Is Active in Treatment through Multiple Lines	*#6 oral presentation* *Session: plenary scientific session* *Sunday 8 December 2019* *14:00 – 16.00 ET*
CD20-TCB (investigational)	Dual CD20-Targeted Therapy With Concurrent CD20-TCB and Obinutuzumab Shows Highly Promising Clinical Activity and Manageable Safety in Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma: Preliminary Results From a Phase Ib Trial	*#1584 poster presentation* *Session: 626* *Saturday 7 December 2019* *17:30-19:30 ET*
	CD20-TCB, a Novel T-Cell-Engaging Bispecific Antibody, Can be Safely Combined with the Anti-PD-L1 Antibody Atezolizumab in Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma	*#2871 poster presentation* *Session: 626* *Sunday 8 December 2019* *18:00-20:00 ET*
Polivy (approved use; updated study results)	Polatuzumab Vedotin Plus Bendamustine with Rituximab in Relapsed/Refractory Diffuse Large B-Cell Lymphoma: Updated Results of a Phase Ib/II Randomized Study	*#4081 poster presentation* *Session: 626* *Monday 9 December 2019* *18:00-20:00 ET*
Polivy (investigational)	Polatuzumab Vedotin Plus Obinutuzumab and Lenalidomide in Patients With Relapsed/Refractory Follicular Lymphoma: Primary Analysis of the Full Efficacy Population in a Phase Ib/II Trial	*#126 oral presentation* *Session: 623* *Saturday 7 December 2019* *10:45 ET*
	Quality of Life (QoL) in Patients With Relapsed/Refractory Non-	*#4767 poster presentation* *Session: 905*

	Hodgkin Lymphoma (NHL) Treated With Polatuzumab Vedotin Plus Rituximab in the ROMULUS Study	*Monday 9 December 2019* *18:00-20:00 ET*
Venclexta/Venclyxto (approved use)	Quantitative Analysis of Minimal Residual Disease (MRD) Shows High Rates of Undetectable MRD after Fixed-Duration Chemotherapy-Free Treatment and Serves As Surrogate Marker for Progression-Free Survival: A Prospective Analysis of the Randomized CLL14 Trial	*#36 oral presentation* *Session: 642* *Saturday 7 December 2019* *08:45 ET*
	Four-Year Analysis of Murano Study Confirms Sustained Benefit of Time-Limited Venetoclax-Rituximab (VenR) in Relapsed/Refractory (R/R) Chronic Lymphocytic Leukemia (CLL)	*#355 oral presentation* *Session: 642* *Sunday 8 December 2019* *07:30 ET*
Venclexta/Venclyxto (investigational)	A Phase 1b Study Evaluating the Safety and Efficacy of Venetoclax in Combination with Azacitidine in Treatment-Naïve Patients with Higher-Risk Myelodysplastic Syndrome	*#568 oral presentation* *Session: 637* *Monday 9 December 2019* *07:45 ET*
	Phase I/II Study Evaluating the Safety and Efficacy of Venetoclax in Combination with Dexamethasone as Targeted Therapy for Patients with t(11;14) Relapsed/Refractory Multiple Myeloma	*#926 oral presentation* *Session: 653* *Monday 9 December 2019* *18:30 ET*
Idasanutlin (investigational)	Updated Results from the Venetoclax (Ven) in Combination with Idasanutlin (Idasa) Arm of a Phase 1b Trial in Elderly Patients (Pts) with Relapsed or Refractory (R/R) AML Ineligible for Cytotoxic Chemotherapy	*#229 oral presentation* *Session: 616* *Saturday 7 December 2019* *14:00 ET*
Hemlibra	Bone and Joint Health Markers	*#626 oral presentation*

(approved use)	in Persons with Hemophilia A (PwHA) Treated with Emicizumab in HAVEN 3	*Session: 322* *Monday 9 December 2019* *10:45 ET*
	Factor VIII Use in the Treatment of Breakthrough Bleeds in Hemophilia A Patients without Inhibitors on Emicizumab Prophylaxis: the Phase 3 HAVEN 3 Study Experience	*#2395 poster presentation* *Session: 322* *Sunday 8 December 2019* *18:00-20:00 ET*
Crovalimab (investigational)	Exposure-Response Relationship of the SMART-Ig Anti-hC5 Antibody crovalimab (SKY59): Results from the umbrella Phase 1/2 COMPOSER Trial in healthy volunteers and PNH patients	*#3745 poster presentation* *Session: 508* *Monday 9 December 2019* *18:00-20:00 ET*

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 idasanutlin, a small molecule which inhibits the interaction of MDM2 with p53; T-cell engaging bispecific antibodies targeting both CD20 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

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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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