Media Release

Roche joins the World Federation of Hemophilia Humanitarian Aid Program

- **Hemlibra donation will provide prophylactic treatment to as many as 1,000 people with haemophilia A over five years in countries where there is little or no access to haemophilia treatment**
- **Donation will substantially increase the number of people receiving prophylactic treatment for haemophilia A through the World Federation of Hemophilia Humanitarian Aid Program**

Basel, 6 February 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that it has joined the World Federation of Hemophilia (WFH) Humanitarian Aid Program, a landmark initiative leading the effort to change the lack of access to care and treatment for people with inherited bleeding disorders in developing countries. Together with Chugai and Genentech, members of the Roche Group, Roche's commitment to the WFH Program consists of a donation of Hemlibra® (emicizumab), a prophylactic treatment for haemophilia A, and funding to deliver the WFH Program's integrated care development training to ensure that local infrastructure and medical expertise are available to optimise and appropriately use the donated Hemlibra.

The donation will provide prophylactic treatment with Hemlibra to as many as 1,000 people with haemophilia A in developing countries, over the course of five years, with a focus on high-need patients, such as people of all ages with factor VIII inhibitors and children without factor VIII inhibitors. Access to prophylactic treatment – the standard of care for haemophilia A to prevent bleeds in most of the developed world – is particularly restricted in developing countries, with limited resources reserved for emergency situations and acute bleeds. [1, 2] The WFH Humanitarian Aid Program currently provides prophylactic treatment to approximately 1,500 people with haemophilia A.

"Thanks to Roche's donation, significantly more people with haemophilia A will be able to receive prophylaxis through the WFH Humanitarian Aid Program. Importantly, the donation will also provide a treatment option for people with haemophilia A with factor VIII inhibitors who previously had very limited or no treatment," said Alain Weill, WFH President. "Increasing access to prophylactic treatments can make a profound difference in countries where haemophilia A remains underdiagnosed and untreated."

Most people with haemophilia in developing countries receive no or inadequate treatment, which significantly affects their health, quality of life and life expectancy. Children with severe haemophilia in countries where there is no access to treatment often do not survive to adulthood. [3]

"We are proud to join the WFH Humanitarian Aid Program, a landmark initiative leading the effort to change the lack of access to care and treatment for people with inherited bleeding disorders in developing countries," said Bill Anderson, CEO Roche Pharmaceuticals. "Our partnership with the WFH reflects our commitment to the haemophilia community and to supporting rapid, broad and sustainable access to Hemlibra for all people with haemophilia A around the world who may benefit from this important treatment option."

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Hemlibra is the only prophylactic medicine that can be given subcutaneously and offers effective bleed control with dosing options as infrequent as every four weeks. [4] Hemlibra has been studied in one of the largest pivotal clinical trial programmes in people with haemophilia A with and without factor VIII inhibitors, including four phase III studies (HAVEN 1, HAVEN 2, HAVEN 3 and HAVEN 4). Hemlibra has been approved for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in people with haemophilia A with factor VIII inhibitors in over 50 countries worldwide. On 4 October 2018, Hemlibra was approved by the US Food and Drug Administration (FDA) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with haemophilia A without factor VIII inhibitors.[3] On 1 February 2019, the EU Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Hemlibra (emicizumab) for routine prophylaxis of bleeding episodes in adults and children with severe haemophilia A without factor VIII inhibitors. Submissions to, and approvals by, other regulatory authorities around the world are ongoing.

To learn more about the WFH and the Humanitarian Aid Program visit https://www.wfh.org/en/humanitarian-aid-program.

About Hemlibra® (emicizumab)
Hemlibra is a bispecific factor IXa- and factor X-directed antibody. It is designed to bring together factor IXa and factor X, proteins required to activate the natural coagulation cascade and restore the blood clotting process for people with haemophilia A. Hemlibra is a prophylactic (preventative) treatment that can be administered by an injection of a ready-to-use solution under the skin (subcutaneously) once-weekly, every two weeks or every four weeks. Hemlibra was created by Chugai Pharmaceutical Co., Ltd. and is being co-developed globally by Chugai, Roche and Genentech. It is marketed in the United States by Genentech as Hemlibra (emicizumab-kxwh), with kxwh as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the US Food and Drug Administration.

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 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 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.

References

[1] Poon MC and Lee A. Individualized prophylaxis for optimizing hemophilia care: can we apply this to both developed and developing nations? Thrombosis Journal. 2016; 14:32.
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[3] Ghosh K, Ghosh K. Management of haemophilia in developing countries: challenges and options. Indian J Hematol Bloos Transfus. 2016 July-Sept; 32(3):347-355.
[4] FDA. Hemlibra Prescribing Information. [Internet; cited 2019 Jan] Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761083s000lbl.pdf

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