Media & Investor Release

New data from phase III HAVEN 6 study reinforce favourable safety and efficacy profile of Roche's Hemlibra in people with moderate or mild haemophilia A

- **Hemlibra continues to demonstrate clinically meaningful bleed control, with 66.7% of participants with moderate or mild haemophilia A experiencing zero treated bleeds at 55.6 weeks median follow-up [1]**
- **New data also reinforce Hemlibra's favourable safety profile, with no new safety signals observed [1]**
- **There is limited information and treatment guidance on moderate and mild haemophilia A, which can lead to delayed or missed diagnoses of bleeding episodes [2]**
- **Hemlibra is approved to treat people of all ages with haemophilia A with factor VIII inhibitors in more than 110 countries and for people of all ages without factor VIII inhibitors in more than 95 countries**

Basel, 11 July 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced results from the primary analysis of the phase III HAVEN 6 study, which show that Hemlibra® (emicizumab) continued to demonstrate a favourable safety profile and effective bleed control in people with moderate or mild haemophilia A, without factor VIII inhibitors.[1] The data will be presented at the 30th International Society on Thrombosis and Haemostasis (ISTH) Annual Congress, on 11 July 2022, in London, United Kingdom, and are planned to support a submission to the European Medicines Agency to update the label for Hemlibra to include non-severe haemophilia A patients.

"We are proud that Hemlibra continues to redefine the standard of care for more people living with haemophilia A," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "The data presented at ISTH this year underscore Roche's commitment to addressing gaps in care for haemophilia A, thereby ensuring that broader populations can potentially benefit from Hemlibra."

In addition to HAVEN 6, data from the CHESS II (Cost of Haemophilia across Europe: a Socioeconomic Survey-II) and CHESS PAEDs studies will also be presented at ISTH 2022. These data show most adults with moderate or mild haemophilia A and more than half of children with moderate haemophilia A may not receive preventative treatments. This can result in worsened clinical burden, as more than 30% of adults and approximately 40% of children with moderate haemophilia A who were not taking preventative treatment in the study experienced at least three bleeds a year.[3]

HAVEN 6 is a phase III, multicentre, open-label, single-arm study evaluating the safety, efficacy, pharmacokinetics and pharmacodynamics of Hemlibra in people with moderate or mild haemophilia A without factor VIII inhibitors. The primary analysis included data from 72 participants (69 men and three women) who warranted prophylaxis; 21 had mild haemophilia A without factor VIII inhibitors and 51 had moderate haemophilia A without factor VIII inhibitors at a median follow-up of 55.6 weeks. At baseline, 37 participants were receiving factor VIII prophylactic treatment and 24 had target joints.[1]

The data show that Hemlibra maintained low treated bleed rates across the study period, with 66.7% of participants experiencing no bleeds that required treatment, 81.9% experiencing no spontaneous bleeds that required treatment, and 88.9% experiencing no joint bleeds that required treatment.[1] Model-based annualised bleed rates (ABR) remained low throughout the evaluation period at 0.9 (95% CI: 0.55-1.52).

The results also show that Hemlibra's safety profile was consistent with findings across various subpopulations of people with haemophilia A, from previous HAVEN and STASEY studies, with no new safety signals observed. The most common adverse event (AE) related to treatment occurring in 10% or more people in the HAVEN 6 study was local injection site reactions (ISRs) (16.7%). Fifteen people (20.8%) reported a Hemlibra-related AE, of which the majority were local ISRs. One participant experienced a grade one thromboembolic event unrelated to Hemlibra. There were no deaths or cases of thrombotic microangiopathy, reinforcing Hemlibra's favourable safety profile.[1]

Hemlibra is approved to treat people with haemophilia A with factor VIII inhibitors in more than 110 countries worldwide and for people without factor VIII inhibitors in more than 95 countries worldwide, including the US and Japan for all severities of haemophilia A, and the EU for only severe haemophilia A. It has been studied in one of the largest clinical trial programmes in people with haemophilia A with and without factor VIII inhibitors, including eight phase III studies.

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 involved in 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 (after an initial once-weekly dose for the first 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 U.S. Food and Drug Administration.

About haemophilia A

Haemophilia A is an inherited, serious disorder in which a person's blood does not clot properly, leading to uncontrolled and often spontaneous bleeding. Haemophilia A affects around 900,000 people worldwide, approximately 35-39% of whom have a severe form of the disorder. People with haemophilia A either lack or do not have enough of a clotting protein called factor VIII. In a healthy person, when a bleed occurs, factor VIII brings together the clotting factors IXa and X, which is a critical step in the formation of a blood clot to help stop bleeding. Depending on the severity of their disorder, people with haemophilia A can bleed frequently, especially into their joints or muscles. These bleeds can present a significant health concern as they often cause pain and can lead to chronic swelling, deformity, reduced mobility and long-term joint damage. A serious complication of treatment is the development of inhibitors to factor VIII replacement therapies. Inhibitors are antibodies developed by the body's immune system that bind to and block the efficacy of replacement factor VIII, making it difficult, if not impossible, to obtain a level of factor VIII sufficient to control bleeding.

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 haematological 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 both FcRH5 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

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each

person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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

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