

Basel, 28 March 2018

## **Roche announces Japanese court ruled in favour of Chugai in Hemlibra patent litigation**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that a Japanese court (Tokyo District Court) ruled in favour of Chugai Pharmaceutical Co., Ltd, a member of the Roche Group, in the patent litigation case relating to Hemlibra® (emicizumab). The court ruled that Hemlibra does not infringe patent 4313531, held by Shire's wholly-owned subsidiaries Baxalta Inc. and Baxalta GmbH.

Hemlibra is the first new medicine in over 20 years to treat people with haemophilia A with inhibitors to factor VIII. Nearly one in three people with severe haemophilia A can develop inhibitors to factor VIII replacement therapies, putting them at greater risk of life-threatening bleeds or repeated bleeding episodes that can cause long-term joint damage.<sup>1</sup> Data from the HAVEN 1 study and interim data from the HAVEN 2 study showed a substantial and clinically meaningful reduction in bleeds in adults, adolescents, and children with haemophilia A with inhibitors. These data also supported approvals by the European Medicines Agency, the US Food and Drug Administration and most recently the Ministry of Health, Labour and Welfare in Japan, of Hemlibra as a treatment for people with haemophilia A with inhibitors. Data from HAVEN 1 and HAVEN 2 are also under review with other health authorities around the world.

### **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. The clinical development programme is assessing the safety and efficacy of Hemlibra and its potential to help overcome current clinical challenges: the short-lasting effects of existing treatments, the development of factor VIII inhibitors and the need for frequent venous access. Hemlibra was created by Chugai Pharmaceutical Co., Ltd. and is being co-developed by Chugai, Roche and Genentech. It is marketed in the United States as Hemlibra (emicizumab-kxwh) for people with haemophilia A with factor VIII inhibitors,

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 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 320,000 people worldwide,<sup>2,3</sup> approximately 50-60% of whom have a severe form of the disorder.<sup>4</sup> 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.<sup>2</sup> 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.<sup>5</sup> A serious complication of treatment is the development of inhibitors to factor VIII replacement therapies.<sup>6</sup> Inhibitors are antibodies developed by the body's immune system that bind to and block the efficacy of replacement factor VIII,<sup>7</sup> making it difficult, if not impossible to obtain a level of factor VIII sufficient to control bleeding.

### **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. 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 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](http://www.roche.com).

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## References

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