Media Release

Roche launches new therapy Emicizumab for people with Hemophilia A on World Hemophilia Day

- Provides treatment options for people living with Hemophilia A with factor VIII inhibitors
- First prophylaxis (preventive) therapy to significantly reduce treated bleeds
- First new class of treatment that can be administered weekly subcutaneously (under the skin) rather than intravenously

Mumbai, 17 April 2019: Roche announced that Emicizumab (Hemlibra®) has been approved in India for Hemophilia A with factor VIII inhibitors. It is indicated as a prophylactic (preventive) treatment to prevent or reduce the frequency of bleeding episodes. Hemlibra is the first weekly subcutaneous (under the skin) prophylaxis injection shown to prevent or reduce the frequency of bleeding episodes and improve the quality of life. 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 Hemophilia A.

All current prophylactic treatment options for people with Hemophilia A with factor VIII inhibitors require intravenous infusions several times a week. Even then, some people may experience joint bleeds that can lead to long-term damage.

The approval of Emicizumab is an important advancement for the entire Hemophilia A community. It is a first-in-class of treatments for people with severe Hemophilia A, with inhibitors in nearly 20 years. The clinical evidence of Hemlibra is supported by a comprehensive and extensive development program in Hemophilia A across all ages.

“The introduction of Emicizumab (Hemlibra®) is a significant milestone in the treatment of Hemophilia A in India and reaffirms our commitment to bring Roche's groundbreaking medicines to patients in India as early as possible,” said Lara Bezerra, Chief Purpose Officer (MD), Roche Pharma India. “This break-through medicine represents a completely new way to manage Hemophilia A and redefines the standard of care. With this new therapy, patients now have a stronger chance of leading a healthy and active life.”

According to World Federation of Hemophilia, India records for the highest number of Hemophilia patients in the world. With the current birth rate in

India being 32/1000, 1,300[1] new patients with Hemophilia are born each year. As of 2018 estimates, there are about 50,000 patients suffering from Hemophilia, of which 20,000 people have been identified and there are still about 30,000 unidentified people with Hemophilia in India[2]. Lack of disease awareness and inadequate infrastructure result in high rates of under-diagnosis and sub-optimal treatment, both of which strongly influence not only the quality of life but also the lifespan of people with Hemophilia.

Hemlibra is approved by multiple regulatory authorities across the world and is now also approved and available in India. In the HAVEN 1 pivotal Phase III clinical study, 62.9% of patients had zero bleeds with Hemlibra prophylaxis. In the HAVEN 2 study, 87% of pediatric patients had zero treated bleeds.

Notes to the Editor

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 Hemophilia A. Hemlibra is a prophylactic treatment that can be administered by an injection of a ready-to-use solution under the skin (subcutaneous).

About Hemophilia A
Hemophilia A is an inherited, serious disorder in which a person's blood does not clot properly, leading to uncontrolled and often spontaneous bleeding. Hemophilia A affects around 320,000[3,4] people worldwide, approximately 50-60% of whom have a severe form of the disorder[5]. People with Hemophilia 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. It is a critical step in the formation of a blood clot to help stop bleeding. Depending on the severity of their disorder, people with Hemophilia A can bleed frequently, especially into their joints or muscles.[3] 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. [6] A serious complication of treatment is the development of inhibitors to factor VIII replacement therapies[7]. Inhibitors are antibodies developed by the body's immune system that bind to and block the efficacy of replacement factor VIII,[8] making it difficult, if not impossible to obtain a level of factor VIII sufficient to control bleeding.

About Roche in Hematology
For more than 20 years, Roche has been developing medicines that redefine treatment in Hematology. Today, we are investing more than ever in our efforts to bring innovative treatment options to people with diseases of the blood. Our portfolio includes MabThera®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab) and an anti-CD79b antibody drug conjugate (polatuzumab

vedotin/RG7596). Roche's dedication to developing novel molecules in Hematology expands beyond malignancy, with the development of Hemlibra® (emicizumab), a bispecific monoclonal antibody for the treatment of Hemophilia A with factor VIII inhibitors.

About Roche India

Roche Products (India) Private Limited is a wholly owned subsidiary of the Roche Group, headquartered in Basel, Switzerland. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche's personalized healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients.

Roche India, which currently trades in pharmaceuticals, as one of its main activities, has products in therapeutic areas such as Oncology, Immunology, Transplantation, Anemia and Rheumatoid Arthritis.

For more information on Roche India, visit www.rocheindia.com.

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