Roche launches new therapy Emicizumab for Hemophilia A patients

https://www.biovoicenews.com/roche-launches-new-therapy-emicizumab-for-hemophilia-a-patients/

By : BioVoice Correspondent - April 17, 2019

New Delhi: Roche has 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 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. 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.