BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

FDA approves new Novo Nordisk treatment for patients with Hemophilia

June 1, 2017 | News

REBINYN is indicated for on-demand treatment and control of bleeding episodes, and the perioperative management of bleeding in adults and children with hemophilia B



Singapore - Novo Nordisk, a US based global healthcare company announced that the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application for REBINYN (Coagulation Factor IX (Recombinant), GlycoPEGylated) for the treatment of adults and children with hemophilia B.

Hemophilia B is a chronic and inherited bleeding disorder that affects approximately 5,000 people in the U.S. People with hemophilia B have deficient blood clotting factor IX activity that results in prolonged or spontaneous bleeding, especially into the muscles, joints or internal organs.

REBINYN is indicated for on-demand treatment and control of bleeding episodes, and the perioperative management of bleeding in adults and children with hemophilia B. REBINYN is not indicated for routine prophylaxis or for immune tolerance induction in patients with hemophilia B.

"We would like to thank the patients who participated in the clinical studies that led to this decision. Thanks to their commitment, we are able to continue to provide new medicines for people with hemophilia," said Bill Breitenbach, Vice President, Biopharmaceuticals Portfolio, Novo Nordisk. "We are committed to the hemophilia community and will continue on our path to bring this new extended half-life treatment to patients who need it."

Novo Nordisk expects to launch REBINYN® in the U.S. in the first half of 2018.