company announcement

Refixia® (nonacog beta pegol; N9-GP) approved in the EU

Bagsværd, Denmark, 6 June 2017 – Novo Nordisk today announced that the European Commission has granted marketing authorisation for Refixia® for the treatment of adolescents and adults with haemophilia B. The authorisation covers all 28 European Union member states.

Refixia® is the brand name for nonacog beta pegol; N9-GP. Refixia® is indicated for prophylaxis, on-demand treatment of bleeding and surgical procedures in adolescent (≥12 years of age) and adult patients with haemophilia B (congenital factor IX deficiency). The efficacy and safety evaluation was based on 115 patients across the five paradigm clinical trials, and the marketing authorisation follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), provided 24 March 2017.

"We are excited about the approval of Refixia® in the EU, and we consider it an important expansion of the treatment options for patients with haemophilia B," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "The strong clinical profile of Refixia® provides haemophilia B patients with better protection against bleeds, even into damaged joints, and an overall improved quality of life."

Novo Nordisk expects to launch Refixia® in the first European countries in the fourth quarter of 2017.

About Refixia®

Refixia® (nonacog beta pegol; N9-GP) is an extended half-life factor IX molecule for replacement therapy in patients with haemophilia B. Glycopegylation, the prolongation technology used for the half-life extension, is a novel approach in haemophilia B. Pegylated products have been approved in haemophilia A and other therapeutic areas. The review of Refixia® was based on the paradigm programme, a phase 3 clinical programme enrolling children and adults with severe or moderately severe haemophilia B. In the programme, 115 previously treated patients had a total of more than 8,800 exposure days for up to 2.7 years of treatment with Refixia®. On 31 May 2017, Novo Nordisk received the US FDA approval of nonacog beta pegol; N9-GP indicated for on-demand treatment and control of bleeding episodes and the perioperative management of bleeding around the time of surgery in adults and children with haemophilia B.

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Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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