company announcement

Esperoct® (turoctocog alfa pegol, N8-GP) approved in the EU

Bagsværd, Denmark, 20 June 2019 – Novo Nordisk today announced that the European Commission has granted marketing authorisation for Esperoct® for the treatment of adolescents (≥12 years of age) and adults with haemophilia A. The authorisation covers all 28 European Union member states.

Esperoct® is the brand name for turoctocog alfa pegol, N8-GP. Esperoct® is indicated for prophylaxis and on-demand treatment of bleeding as well as for surgical procedures in adolescents and adults with haemophilia A (congenital factor VIII deficiency). The efficacy and safety evaluation was based on the results from the largest pre-registration clinical programme conducted in haemophilia A, with inclusion of 270 previously treated people (PTPs) with severe haemophilia A and more than 5 years of clinical exposure. The marketing authorisation follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), provided 26 April 2019.

"We are excited about the approval of Esperoct® in the EU, and we consider it an important expansion of the treatment options for patients with haemophilia A," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We are confident that Esperoct® will provide people with haemophilia A a simple and less burdensome, predictable dosing regimen for prophylaxis as well as treatment of bleeding episodes, resulting in improved quality of life."

Novo Nordisk expects to launch Esperoct® in the first European countries during the second half of 2019.

About Esperoct®
Esperoct® (turoctocog alfa pegol, N8-GP) is an extended half-life factor VIII molecule for replacement therapy in people with haemophilia A, which provides a 1.6-fold half-life prolongation in adults/adolescents compared to standard half-life factor VIII products. Esperoct® was shown to provide effective routine prophylaxis in people with severe haemophilia A through a simple, predictable dosing regimen of one injection every 4 days in adults and adolescents. Esperoct ® provided effective prophylaxis with an annual

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bleeding rate of 1.18 when dosed at 50 IU/kg every 4 days in adults and adolescents. Furthermore, Esperoct® was found to be efficacious in treatment and control of bleeding episodes and perioperative management. Across the clinical trials and age groups, Esperoct® was well tolerated and no safety concerns were identified. The overall safety profile of Esperoct® is similar to what has been reported for other long-action FVIII products.

Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,200 people in 80 countries and markets its products in more than 170 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 and YouTube.

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