ESPEROCT® is now approved in Canada for the Treatment of Hemophilia A in both Children and Adults

New treatment can help Canadians living with hemophilia A better manage their bleeding episodes

TORONTO, July 12, 2019 – Novo Nordisk announced today that Health Canada has approved ESPEROCT® (Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), PEGylated) for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding.[1]

"Canadians living with hemophilia A are at risk of bleeding for longer periods of time. If not treated appropriately, those bleeding episodes, particularly into joints and muscles, can be painful, lead to joint damage and muscular atrophy over the patient's lifetime and in some cases can be life threatening," said Dr. Anthony Chan, OOnt, Professor of Paediatrics, McMaster University. "ESPEROCT® has been shown to be effective in reducing the risk of bleeding episodes among patients."

Health Canada's approval is based on the findings from three multinational, open-label, non-controlled trials in male subjects with severe hemophilia A, which is defined as having less than 1 per cent of the normal level of factor VIII in the blood.[2,3] All subjects were previously treated, having received other FVIII products for more than 150 exposure days for adolescents and adults and more than 50 exposure days for pediatric subjects.[4]

"The Canadian Hemophilia Society advocates for access to the widest possible range of coagulation therapies and welcomes the regulatory approval of this additional option for the treatment of hemophilia A," said Paul Wilton, President, Board of Directors, Canadian Hemophilia Society.

Overall, ESPEROCT® was shown to provide effective prophylaxis and maintain a low median ABR of 1.18 when dosed at 50 IU/kg every 3-4 days in adults and adolescents (those aged 12 years and over) and a median ABR of 1.95 in children under 12 years of age when dosed twice weekly at 60 IU/kg (50-75 IU/kg).[5]

Across the clinical trials and age groups, ESPEROCT® was well tolerated and had no safety concerns identified.[6] The safety profile of ESPEROCT® is similar to what has been reported for other long-action FVIII products.[7]

About Hemophilia A

Hemophilia A is an X-linked, recessive disorder caused by a deficiency of functional plasma clotting factor VIII (FVIII), which may be inherited or arise from spontaneous mutation.[8] One out of three cases for the estimated 2,500 Canadians living with hemophilia A are caused by a new genetic mutation. [9,10] The most common symptom associated with hemophilia is a bleeding problem, which can lower the overall quality of life for many patients.[11]

About ESPEROCT®

ESPEROCT® (turoctocog alfa pegol, N8-GP) is an extended half-life factor VIII molecule for replacement therapy in people with hemophilia A. In adults, the half-life for ESPEROCT® was determined to be 19 hours compared to 12 hours for unmodified FVIII products, using the chromogenic assay.[12]

About Novo Nordisk

Novo Nordisk is a global healthcare company with 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, hemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,200 people in 79 countries, and markets its products in more than 170 countries. For more information, visit novonordisk.ca, Twitter and YouTube.

Further information

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