press release

Novo Nordisk announces the availability of Zonovate® for the treatment of patients with hemophilia A in Quebec

Mississauga, Canada, April 11, 2018 – Today, in Quebec, Novo Nordisk announced the availability of Zonovate® (Antihemophilic Factor (Recombinant, B-Domain Truncated)), for use in adults and children with hemophilia A (congenital Factor VIII deficiency or classic hemophilia) for treatment and control of bleeding episodes, perioperative management and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.[1]

Hemophilia is a hereditary condition, passed on from mother to child at the time of conception. Hemophilia A is a rare disorder, affecting fewer than 1 in 10,000 people, or about 2,500 Canadians.[2]

“With its history of success in hemophilia care, Novo Nordisk has shown it can perform as a trustworthy partner,” said Smaranda Ghibu, Acting President and Vice-President, Public Relations and General Secretariat of Héma-Québec. “We look forward to initiating what we expect to be a productive relationship with Novo Nordisk in the supply of important medicines to patients in Québec."

The Health Canada approval of Zonovate® was granted based on the guardian™ clinical program, one of the largest and most comprehensive clinical trial programs of a recombinant Factor VIII to-date. The guardian™ clinical trials were conducted to evaluate the safety and efficacy of Zonovate® in the prevention and treatment of bleeds in previously treated patients with severe hemophilia A (Factor VIII activity ≤1%).

Eighty-nine per cent, and 95 per cent of bleeds experienced by adult/adolescent patients and pediatric patients, respectively, in the guardian™1 and guardian™3 trials were controlled with 1 or 2 infusions. Patients who took Zonovate® prophylactically had a median of 1.7 bleeds per year in the extension trial (guardian™2). The most common adverse reactions (may affect up to 1 in 10 people) were injection site reactions (2.3 per cent) and increased hepatic enzymes (1.4 per cent).[3]

About Zonovate®

Zonovate® was approved by Health Canada on December 8, 2014 and has been launched in 11 regions including the United States. Zonovate® is used to treat and prevent bleeding episodes in patients with hemophilia A. In patients with hemophilia A, Factor

VIII is missing or not working properly. Zonovate® replaces this faulty or missing Factor VIII and helps blood to form clots at the site of bleeding.[4]

Zonovate® offers purity, reliability, and enhanced portability, with the ability to store at room temperature, at ≤30°C for a single period up to 12 months. Zonovate® can also be kept at ≤30°C for up to four hours after reconstitution. Zonovate® offers purity through a five-step purification process.[5]

About guardian™

Three trials have been conducted to evaluate the safety and efficacy of Zonovate®. guardian™1 enrolled adults and adolescents, and guardian™3 enrolled children. Upon completion of the initial trials, patients from both guardian™1 and guardian™3 were eligible to participate in the guardian™2 extension trial. Data from guardian™1 and guardian™3 as well as data from the first part of the guardian™2 extension trial were analyzed at the time of submission for approval. The interim analysis on 187 patients who continued to receive treatment in the ongoing guardian™2 trial showed a median ABR of 1.7.

About Hemophilia A

Hemophilia is a chronic, inherited bleeding disorder that primarily affects males. People with hemophilia A are either missing or have a malfunctioning factor VIII protein, which is essential for proper blood clotting, and they tend to bleed longer than most or to bleed internally into joints, muscles or organs because they are missing this clotting factor. To manage the disease and stop bleeding, people with hemophilia A must replace the missing factor VIII protein, which is accomplished by intravenous injection of the clotting factor.[6]

About Novo Nordisk

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: hemophilia, 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. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Further information

Media:
Kate Hanna 905-629-6612 kxyh@novonordisk.com

References

1 Zonovate® Product Monograph. Novo Nordisk Canada Inc. May 19, 2017.
2 Canadian Hemophilia Society. http://www.hemophilia.ca/en/bleeding-disorders/hemophilia-a-and-b/what-is-hemophilia/. Accessed March 19, 2018.
3 Zonovate® Product Monograph. Novo Nordisk Canada Inc. May 19, 2017.
4 Zonovate® Product Monograph. Novo Nordisk Canada Inc. May 19, 2017.
5 Zonovate® Product Monograph. Novo Nordisk Canada Inc. May 19, 2017.

6 Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al; *Treatment Guidelines Working Group on Behalf of the World Federation of Hemophilia. Guidelines for the management of hemophilia*. Hemophilia. 2013;19(1):e1-e47.