# press release

## Novo Nordisk expands product offerings in Canada for the treatment of Hemophilia A in both children and adults, with availability of ESPEROCT® and ZONOVATE®

*Newly available treatments can help Canadians living with hemophilia A better manage their bleeding episodes*

**Mississauga, ON, April 1, 2022** – Novo Nordisk announced today that it is extending its product offerings to better support Canadians living with hemophilia A, as both ESPEROCT® (Antihemophilic Factor VIII (Recombinant, B-Doman Truncated), PEGylated) and ZONOVATE® (Antihemophilic Factor (Recombinant, B-Domain Truncated) are now publicly available through Canadian Blood Services starting April.1, 2022. ZONOVATE® has been available in Quebec through Hema-Quebec from April 2018.

"As part of our continued commitment to provide support to Canadians living with rare diseases, we are pleased to expand our product portfolio across Canada to address individual patient needs," says John Burrows, Vice President, Rare Disease, Novo Nordisk Canada Inc. "It's important that people living with hemophilia A have access to treatment options that are safe, effective, and have the ability to support better control of bleeding episodes and improve overall health outcomes."

### About ESPEROCT® and ZONOVATE®

ESPEROCT® (turoctocog alfa pegol) is a long-acting recombinant factor VIII molecule for replacement therapy in people with hemophilia A. ESPEROCT® was developed by extending the half-life of ZONOVATE® (turoctocog alfa) using site-specific glycoPEGylation technology.

### ESPEROCT®

ESPEROCT® is a long-acting recombinant coagulation Factor VIII product that helps children and adults living with hemophilia A to better manage bleeding episodes.[1] It received Health Canada approval in 2019 for the treatment of hemophilia A (congenital Factor VIII deficiency) in both adults and children. Approval of ESPEROCT® was based on the pathfinder trial™ clinical program.

It is indicated for:

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

In adults, the half-life for ESPEROCT® was determined to be 19 hours compared to 12 hours for unmodified FVIII products.[2] ESPEROCT® offers multiple storage options including temperatures up to 30°C to 40°C prior to reconstitution.[3]

ESPEROCT® was shown to provide effective prophylaxis and maintain a low median annual bleeding rate (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).[4] Pharmacokinetic predictions showed that patients dosed every 3-4 days in all age groups were above 5% FVIII activity (i.e. in the range of mild hemophilia) for the majority of time (72-95% of time).[5]

Across clinical trials and age groups, ESPEROCT® was well tolerated with the most common side effects being skin reactions where the injection was given, itching (pruritus), redness of skin (erythema) and rash. The safety profile of ESPEROCT® is similar to what has been reported for other long-action FVIII products.[6]

For more information on ESPEROCT® including important safety information please visit NovoNordisk.ca or view the product monograph here.

**ZONOVATE®**

ZONOVATE® (Antihemophilic Factor (Recombinant, B-Domain Truncated), is approved for use in adults and children with hemophilia A (congenital Factor VIII deficiency or classic hemophilia).[7] It is indicated for:

- Treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

ZONOVATE® received Health Canada approval in 2014 and became available for patients in Quebec in 2018. Approval of ZONOVATE® was based on the guardian™ clinical program.

For more information on ZONOVATE® including important safety information please visit NovoNordisk.ca or view the product monograph here.

**About Hemophilia A**

Hemophilia A – commonly referred to as classical hemophilia - impacts an estimated 1 in 10,000 people, or about 2,500 Canadians.[8] It is a rare, hereditary bleeding disorder and is caused by insufficient levels of a blood protein called factor VIII. Factor VIII is a clotting factor. Clotting factors are specialized proteins that are essential for proper clotting, the process by which blood clumps together to plug the site of a wound to stop bleeding. If left untreated, hemophilia A can lead to serious health complications.

**About Novo Nordisk**

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 42,700 people in 80 countries and markets its products in around 170 countries.

For more information, visit novonordisk.ca, or @NovoNordiskCA on Twitter.

**Further information**

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[1] ESPEROCT® Product Monograph. Novo Nordisk Canada Inc. May 6, 2020 (Date of revision)

[2] ESPEROCT® Product Monograph. Novo Nordisk Canada Inc. May 6, 2020 (Date of revision)

[3] ESPEROCT® Product Monograph. Novo Nordisk Canada Inc. May 6, 2020 (Date of revision)

[4] ESPEROCT® Product Monograph. Novo Nordisk Canada Inc. May 6, 2020 (Date of revision)

[5] ESPEROCT® Product Monograph. Novo Nordisk Canada Inc. May 6, 2020 (Date of revision)

[6] ESPEROCT® Product Monograph. Novo Nordisk Canada Inc. May 6, 2020 (Date of revision)

[7] ZONOVATE® Product Monograph. Novo Nordisk Canada Inc. April 14, 2021 (Date of Revision).

[8] Canadian Hemophilia Society. Hemophilia A and B. Retrieved from https://www.hemophilia.ca/hemophilia-a-and-b/. Accessed February 2022.