

## press release

### **Health Canada approves Alhemo™, the first subcutaneous prophylactic treatment for people living with hemophilia B with inhibitors**

New treatment option for Canadians living with rare and serious X-chromosome linked congenital bleeding disorder

**Mississauga, ON, April 17, 2023** – Health Canada has approved Alhemo™, the first anti-tissue factor pathway inhibitor (TFPI) and subcutaneous prophylactic treatment for people living with hemophilia B with inhibitors.<sup>1</sup> Alhemo™ is indicated for the treatment of patients over the age of 12 with hemophilia B who have FIX inhibitors and require routine prophylaxis to prevent or reduce the frequency of bleeding episodes.<sup>1</sup>

Hemophilia B is a hereditary bleeding condition, which is the result of a missing or faulty protein (factor IX) that prevents blood from clotting normally.<sup>1</sup> In Canada, hemophilia B impacts an estimated 1 in 50,000 people or about 600 Canadians.<sup>2</sup> Depending on the severity of the condition, symptoms of hemophilia can range from surface bruising and bleeding due to minor bumps or twists, bleeding into joints, soft tissues and muscles, bleeding in the mouth from a cut, bitten tongue or loss of tooth, as well as more bleeding during menstruation.<sup>3</sup>

Alhemo™ is used for hemophilia B patients who have developed “factor IX inhibitors” that prevent replacement factor IX therapies from working properly.<sup>1</sup> Alhemo™ works through a monoclonal antibody which recognizes a protein (TFPI) that prevents clotting and binding to this protein to increase clotting and stop bleeding in hemophilia B patients.<sup>1</sup>

“We are pleased to have the approval of Alhemo™ to expand our portfolio of innovative options for Canadians living with hemophilia B with inhibitors,” says John Burrows, Vice President, Rare Disease, Novo Nordisk Canada Inc. “Hemophilia B is a rare disorder and those with an inhibitor to standard therapy have limited options. Living with hemophilia B can be an ongoing struggle as a result of the inability to manage uncontrolled bleeding. The approval of treatments like Alhemo™ will provide benefits to both patients and caregivers. This new treatment option will allow them to take control of their bleeding episodes effectively, improving their quality of life.”

Alhemo™ builds upon Novo Nordisk's commitments to the hemophilia community. Previously, Health Canada approved Rebinyn® for hemophilia B patients, as well as NiaStase RT® for those patients with hemophilia B who have developed inhibitors. While Rebinyn® is an anti-hemophilic factor<sup>4</sup> and NiaStase RT® is an activated recombinant human blood coagulation Factor VII<sup>5</sup>, Alhemo™ is the first anti-TFPI and subcutaneous prophylactic treatment for people living with hemophilia B with inhibitors.<sup>1</sup>

### **About Hemophilia B**

Hemophilia B – commonly referred to as factor IX deficiency hemophilia – impacts 1 in 50,000 people or about 600 Canadians.<sup>2</sup> It is a rare and serious X-chromosome linked congenital bleeding disorder that affects the blood's ability to clot caused by missing or faulty coagulation factor IX (FIX).<sup>1</sup> If left untreated, hemophilia B can lead to serious health complications.

### **About Alhemo™**

Alhemo™ was approved by Health Canada on March 10, 2023, making Canada the first country in the world to receive approval.<sup>1</sup> Alhemo™ is used to treat adolescent and adult patients with hemophilia B (congenital factor IX [FIX] deficiency) who have FIX inhibitors and require routine prophylaxis to prevent and reduce the frequency of bleeding episodes.<sup>1</sup> In patients with hemophilia B, a bleeding condition people are born with, a missing or faulty protein (factor IX) prevents blood from clotting normally.<sup>1</sup> Alhemo™ is used for hemophilia B patients who have developed "factor IX inhibitors" that prevent replacement factor IX therapies from working properly.<sup>1</sup>

Alhemo™ is the first anti-TFPI (Tissue Factor Pathway Inhibitor) approved worldwide. It represents the first approved subcutaneous prophylaxis treatment for people living with Hemophilia B.

For more information on Alhemo™ including important safety information please visit [NovoNordisk.ca](https://NovoNordisk.ca) or view the product monograph [here](#).

### **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 54,400 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.com](https://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).*

### **Further information**

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<sup>1</sup> Alhemo™ Product Monograph. Novo Nordisk Canada Inc. March 10, 2023.

<sup>2</sup> Canadian Hemophilia Society. (n.d.). *Hemophilia A and B*. <https://www.hemophilia.ca/hemophilia-a-and-b/>

<sup>3</sup> Canadian Hemophilia Society. (n.d.). *Symptoms of Hemophilia*. <https://www.hemophilia.ca/symptoms-of-hemophilia/>

<sup>4</sup> REBINYN® Product Monograph. Novo Nordisk Canada Inc. November 22, 2022.

<sup>5</sup> NiaStase RT® Product Monograph. Novo Nordisk Canada Inc. October 18, 2018.