press release

European regulatory authority adopts positive opinion for Novo Nordisk's Alhemo® (concizumab), recommending label expansion to treat haemophilia A and B without inhibitors

- Pending European Commission (EC) approval, Alhemo® will become available to all adult and paediatric patients 12 years and older living with severe haemophilia A and moderate or severe haemophilia B without inhibitors.
- This positive opinion by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) is based on results from the explorer8 trial, which showed that Alhemo® reduced spontaneous and traumatic bleeds for patients living with haemophilia A and B without inhibitors compared with no prophylaxis[1].
- If approved by the EC, Alhemo®, with its pen-injector device, has the potential to be an efficacious and easy-to-use option for patients with haemophilia A and B without inhibitors[1-3].

Bagsværd, Denmark, 25 July 2025 – Novo Nordisk today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending an update of the Alhemo® (concizumab) label to include the treatment of severe haemophilia A and moderate or severe haemophilia B without inhibitors.

"If approved by the European Commission, this label update would extend Alhemo®'s convenient once-daily, under-the-skin administration to patients living with haemophilia without inhibitors, providing an efficacious prophylactic choice," said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk. "Each person living with haemophilia has individual and evolving needs. With its user-friendly, pre-filled, portable pen, we believe that Alhemo® has the potential to offer even more patients an individualised and flexible treatment."

The positive CHMP opinion is based on the results from the phase 3 explorer8 trial, which met its primary endpoint. The results demonstrated that Alhemo® prophylaxis compared with no prophylaxis treatment led to an 86% reduction and 79% reduction in treated spontaneous and traumatic bleeds for patients living with haemophilia A without inhibitors and haemophilia B without inhibitors[1], respectively. In this trial, Alhemo® showed a favourable safety profile in patients with haemophilia A and B without inhibitors[1].

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Patient-Reported Outcome (PRO) data from the explorer8 study further indicated an improvement in health-related quality of life and reduction in treatment burden with Alhemo® treatment compared with no prophylaxis[3]. Specifically, trends favouring Alhemo® over prophylaxis were observed in the short-form health survey (SF-36v2) and Haemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) results, in patients with haemophilia A and haemophilia B; these included the change in "bodily pain" and "physical functioning" from baseline to week 24 in the survey, and the Haem-A-QoL "total score" and the "physical health" domain score[3]. Treatment preference results showed patients were also in favour of Alhemo® over no prophylaxis or previous treatment, with 70.9% of respondents indicating they prefer Alhemo® over their previous haemophilia treatment[3].

Following the positive opinion from the CHMP, Novo Nordisk expects the European Commission (EC) to approve the label update within approximately two months.

About Alhemo® (concizumab)

Alhemo® (concizumab) is an anti-tissue factor pathway inhibitor (TFPI), monoclonal antibody designed to block a protein in the body that stops blood from clotting. By blocking TFPI, Alhemo® ensures the production of thrombin, which helps to clot the blood and prevent bleeding[4]. Alhemo® is currently approved in Europe[5], the United States[6], India[7], Brazil[8] and Switzerland[9] for the treatment of adolescents and adults (12 years or older) with haemophilia A and B with inhibitors. In Japan[10] and Australia[11], Alhemo® is currently approved for the treatment of adolescents and adults (12 years or older) with haemophilia A and B with and without inhibitors. In all approved countries, it is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

About the explorer8 study

Explorer8 is a multicentre, open-label, randomised, phase 3a clinical trial aimed to establish the efficacy and safety profile of Alhemo® in adults and paediatric patients 12 years of age and older living with congenital severe haemophilia A or moderate or severe haemophilia B without inhibitors[1,12]. In explorer8, 148 patients were randomly assigned in a 1:2 ratio to receive no prophylaxis (arm 1, n=21) or Alhemo® prophylaxis (arm 2, n=42), and 85 were nonrandomly assigned to receive Alhemo® prophylaxis (arms 3 and 4). The initial loading dose of Alhemo® was 1 mg per kilogram of body weight, followed by 0.2 mg per kilogram daily, and potentially individualised on the basis of concizumab plasma concentration as measured at Week 4[1,12]. The primary analysis was carried out when all patients in arms 1 and 2 completed at least 24 or 32 weeks, respectively, and compared the number of treated spontaneous and traumatic bleeding episodes, measured as annualised bleeding rate, between arms 1 and 2[1,12]. Supportive secondary endpoints, such as percent of patients experiencing zero bleeds, are reported as descriptive results only[1,12]. The trial is still ongoing in the extension phase and is expected to complete in 2028[1,12].

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About haemophilia

Haemophilia is a rare inherited bleeding disorder that impairs the body's ability to make blood clots, a process needed to stop bleeding. It is estimated to affect approximately 1,125,000 people worldwide[13]. Due to the nature of haemophilia being an x-linked recessive disorder, it often presents differently in males compared with females, with roughly 88% of people diagnosed with haemophilia worldwide being male[14,15]. There are different types of haemophilia, which are characterised by the type of clotting factor protein that is defective or missing. Haemophilia A is caused by a missing or defective clotting Factor VIII (FVIII), and haemophilia B is caused by a missing or defective clotting Factor IX (FIX).

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 serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 77,400 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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