Press release

FREHEMGO® (denecimig) approved in the EU for haemophilia A, with a choice of monthly, every-two-weeks or weekly dosing

- European Commission (EC) grants marketing authorisation for FREHEMGO® (denecimig) for haemophilia A (congenital FVIII deficiency), with or without inhibitors, in adults and children.
- FREHEMGO® is the first FVIIIa mimetic to offer once-monthly, once-every-two-weeks and once-weekly prophylaxis in a single-use pre-filled pen.
- Novo plans to launch FREHEMGO® in the first European countries in the year ahead.

Bagsværd, Denmark, 13 November 2026 – Novo today announced that the European Commission has granted marketing authorisation for FREHEMGO® (denecimig) as routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with haemophilia A (congenital FVIII deficiency), with or without inhibitors. The authorisation follows the positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency in September 2026.

FREHEMGO® is a next-generation FVIIIa mimetic bispecific antibody given as an injection under the skin. People with haemophilia A, with or without inhibitors, and their healthcare teams can choose between once-monthly, once-every-two-weeks or once-weekly dosing, using a single-use pre-filled pen.

"Living with haemophilia means constantly planning around the risk of bleeding, often from early childhood. Each advance in treatment gives people with haemophilia and their families more freedom to focus on other aspects of life" said Maria Elisa Mancuso, Medical Member of the Board of Directors of World Federation of Hemophilia (WFH) and Senior Hematology Consultant at the Centre for Thrombosis and Hemorrhagic Diseases of IRCCS Humanitas Research Hospital in Rozzano, Milan, Italy. "Having more treatment options to discuss with their clinicians allows people to consider what best fits their everyday lives—at school, at work, in sport and within their families—and make informed decisions that reflect their individual needs and priorities."

The approval is based on results from the FRONTIER clinical trial programme. In the pivotal FRONTIER2 trial, denecimig significantly reduced annualised bleeding rates compared with prior clotting factor prophylaxis and on-demand treatment in people with haemophilia A, with or without inhibitors[1]. In children younger than 12 years, results from FRONTIER3 were consistent with the efficacy seen in adolescents and adults[2]. Across the FRONTIER programme, denecimig has shown consistently low mean annualised bleeding rates, with a substantial proportion of participants experiencing zero treated bleeds[1-3]. In the FRONTIER5 trial, direct switching from emicizumab to

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denecimig showed no new safety signals, a clear preference for the denecimig pen over previous administration methods and a sustained increase in thrombin generation into the normal range over the treatment period, without causing thrombin levels that might pose a thrombotic risk[4,5].

"This approval reflects the strength and consistency of the FRONTIER programme, which showed strong bleed protection across adults and children, with and without inhibitors," said Martin Holst Lange, Chief Scientific Officer and Executive Vice President of Research & Development at Novo. "It's the result of many years of work by our scientists, the trial investigators and the people with haemophilia A who took part in our studies. Together, they have helped bring the haemophilia community a treatment option that minimises trade-offs in care."

FREHEMGO® has also been approved in Saudi Arabia and is under review by the US Food and Drug Administration (FDA) and other regulatory authorities.

What is haemophilia?

Haemophilia is a rare inherited bleeding disorder that impairs the body's ability to make blood clots, a process needed to stop bleeding[6]. It is estimated to affect approximately 1,125,000 people worldwide[7]. There are different types of haemophilia, which are characterised by the type of clotting factor protein that is defective or missing[6]. Haemophilia A is caused by a missing or defective clotting Factor VIII (FVIII). Inhibitors are an immune system response to the clotting factors in replacement therapy. Currently, it is estimated that up to 30% of people living with severe haemophilia A develop inhibitors that can cause replacement therapies to stop working[8].

About FREHEMGO® (denecimig)

FREHEMGO® (denecimig) is a FVIIIa mimetic bispecific antibody for routine prophylaxis in people living with haemophilia A, with or without inhibitors, offering once-monthly, once-every-two-weeks or once-weekly dosing[1-3]. FREHEMGO®, which is administered under the skin using a single-use pre-filled pen, 'mimics' the role of FVIIIa by bridging Factor IXa and Factor X[9]. This action mimics the cofactor function of FVIIIa, which helps restore the body's thrombin generation capacity, helping blood to clot[9]. FREHEMGO® is approved in the EU and Saudi Arabia.

About the FRONTIER trials

The FRONTIER clinical programme includes FRONTIER1–5 and investigates denecimig as a prophylactic treatment to prevent bleeding episodes across paediatric and adult populations with haemophilia A, with or without inhibitors[2-4,10,11].

FRONTIER2, FRONTIER3 and FRONTIER4 formed the basis of the denecimig Marketing Authorisation Application (MAA) submission. FRONTIER2 evaluated denecimig once-monthly and

once-weekly in adults and adolescents 12 years of age and older; FRONTIER3 evaluated denecimig once-monthly and once-weekly in children below the age of 12; FRONTIER4 was an open-label extension trial evaluating the efficacy of denecimig once-every-two-weeks as well as investigating the long-term safety of denecimig across all dosing regimens (once-monthly, once-every-two-weeks and once-weekly) in people with haemophilia A, with or without inhibitors[2,3,11]. FRONTIER5 evaluated the safety of switching directly from emicizumab to denecimig prophylaxis, as well as device preference[4].

Novo is the global healthcare company that believes lasting health starts now. For over a century, we've combined leading scientific expertise with a deep understanding of people's lives. We develop treatments and support that help millions of people make progress they can see, feel and sustain now and in the future. Every day, over 66,500 employees around the world advance our purpose to drive change for lasting health. Through our partnerships, programmes and investments, we're working to prevent disease, expand access to treatments and reduce our environmental impact to help even more people live healthier lives. For more information, visit novonordisk.com and follow us on Instagram, LinkedIn, TikTok, Facebook, X and YouTube.

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