Company announcement

CHMP recommends EU approval of FREHEMGO® (denecimig), the first factor VIIIa mimetic offering monthly, once every two weeks and weekly dosing in a pre-filled pen, for the treatment of haemophilia A

- FREHEMGO® (denecimig) has been recommended by CHMP for approval in the EU for the treatment of haemophilia A (congenital FVIII deficiency), with or without inhibitors for 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 expects to launch FREHEMGO® in the first European countries in Q4 2026 and broadly across the EU starting early 2027

Bagsværd, Denmark, 17 September 2026 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorisation for FREHEMGO® (denecimig) to treat haemophilia A (HA), with or without inhibitors, in adults and children.

FREHEMGO® is a next-generation factor VIIIa mimetic bispecific antibody, designed as a routine prophylaxis to prevent or reduce the frequency of bleeding episodes in people living with HA, with or without inhibitors.

The CHMP recommendation is based on the FRONTIER trial programme. In the pivotal FRONTIER 2 trial, denecimig significantly reduced annualised bleeding rate compared to prior clotting factor prophylaxis and on-demand treatment in people with HA, with or without inhibitors. In children younger than 12 years, results from FRONTIER 3 were consistent with the efficacy observed in adolescents and adults.[1-2] Across the FRONTIER programme, denecimig has demonstrated consistently low mean annualised bleeding rates, generally below 1 in the reported phase 3 population, and with a substantial proportion of participants experiencing zero treated bleeds.[1-3] Furthermore, in the FRONTIER 5 trial, no new safety signals were identified following direct

[1] NCT5053139; Mancuso ME, Chan AKC, Shanmukhaiah C, et al. *N Engl J Med*. 2026; doi: 10.1056/NEJMoa2517384

[2] NCT05306418

[3] NCT05685238

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switching from emicizumab to denecimig prophylaxis. The study also showed a clear preference for the denecimig device.[4]

"The recommendation by the CHMP for approval of FREHEMGO® builds on Novo's commitment of over 40 years in haemophilia and marks an important advancement for people living with haemophilia A, with or without inhibitors", said Mike Doustdar, president and CEO of Novo. "The combination of strong bleed protection, flexible dosing frequency and a prefilled pen offers a differentiated treatment option that can reduce treatment burden and give people with haemophilia A greater freedom in managing their disease."

In September 2025, Novo submitted denecimig for review to the US Food and Drug Administration (FDA) through a Biologics License Application (BLA).

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.

FRONTIER2, FRONTIER3 and FRONTIER4 formed the basis of the denecimig Marketing Authorisation Application (MAA) submission. FRONTIER2 evaluated denecimig treatment once every month and once every week in adults and adolescents 12 years of age and older; FRONTIER3 evaluated denecimig treatment once every month and once every week in children below the age of 12; FRONTIER4 was an open-label extension trial evaluating the efficacy of denecimig once every two weeks (Q2W) as well as investigating the long-term safety of denecimig across all dosing regimens (once every month, once every two weeks, and once every week) in subjects with haemophilia A, with or without inhibitors.

About FREHEMGO® (denecimig)
FREHEMGO® (denecimig) is an FVIIIa mimetic bispecific antibody designed with the aim to deliver once monthly, every two weeks and weekly prophylaxis for people living with haemophilia A, with or without inhibitors. FREHEMGO®, which is administered under the skin, 'mimics' the role of FVIIIa by bridging factor IXa and factor X. This action mimics the cofactor function of FVIIIa, which helps restore the body's thrombin generation capacity, helping blood to clot. FREHEMGO® is currently pending marketing approval from the EMA and other regulatory authorities.

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 67,000 employees around the world advance our purpose to drive change for lasting health. Through our partnerships,

[4] NCT05878938; Hermans C, Benson G, Matino D, et al. *J Thromb Haemost.* 2026; doi: 10.1016/j.jtha.2026.09.004

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. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com and follow us on Instagram, LinkedIn, TikTok, Facebook, X and YouTube.

Publication of inside information pursuant to Market Abuse Regulation, Article 17.

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