

Company announcement

Novo provides update on the denecimig Biologics License Application (BLA) in the US

- The US Food and Drug Administration (FDA) has informed Novo that the BLA review of denecimig for the treatment of haemophilia A is still ongoing. The FDA has not communicated a new timeline for regulatory action on the BLA
- The FDA has informed Novo that the ongoing facility remediation activities are the cause for extension of the Agency's review. The FDA has not identified any deficiencies related to the clinical efficacy or safety data submitted in the denecimig BLA
- Novo is actively working with the FDA, addressing the Agency's requests for remediations related to the manufacturing facility. The extended FDA review time for the denecimig BLA has no impact on Novo's financial outlook for 2026 and pending regulatory decision, Novo aims to launch denecimig in the US in the first half of 2027

Bagsværd, Denmark, 02 October 2026 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has informed Novo that the BLA review of denecimig for the treatment of haemophilia A, with or without inhibitors in adults and children, is still ongoing. The FDA has not communicated a new timeline for expected regulatory action on the BLA.

Novo submitted a BLA for denecimig for the treatment of haemophilia A in adult and paediatric patients to the US FDA for review in September 2025, with an anticipated regulatory decision in the third quarter of 2026. Following this submission, the FDA performed a pre-license inspection of the manufacturing site and provided feedback. Today, the FDA has informed Novo that the ongoing facility remediation activities are the cause for extension of the Agency's review.

“Haemophilia A patients should expect more from their standard of care,” said Mike Doustdar, president and CEO of Novo. “As Novo prepares to bring denecimig to market, our ambition is to help make better care something they can count on. Novo is already in the process of addressing the FDA's requests as efficiently as possible and continuing to work closely with the Agency toward bringing denecimig to patients in the US.”

The Agency has not identified deficiencies related to the clinical efficacy or safety data of denecimig demonstrated in the FRONTIER clinical trial programme. Novo is continuing implementation of the facility remediation activities in response to the FDA's feedback and is

working closely with the Agency to address the outstanding requirements. The feedback on the manufacturing site does not impact other marketed Novo products.

The additional FDA review time does not have an impact on Novo's financial outlook for 2026. Pending regulatory decision, Novo aims to launch denecimig in the US in the first half of 2027.

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 denecimig

Denecimig is a 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. Denecimig, 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. On 17 September, denecimig received a positive CHMP opinion and is currently pending marketing approval from the EMA and under review by 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, 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](https://www.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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