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Novo Nordisk reports long-term Phase III data for denecimig in haemophilia A

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The FRONTIER4 extension study supports denecimigâ??s potential as a flexible subcutaneous prophylaxis option across age groups and dosing schedules.

Novo Nordisk has reported interim Phase III FRONTIER4 extension data for denecimig, also known as Mim8, in people with haemophilia A.

The data were presented at the International Society on Thrombosis and Haemostasis Congress 2026 in Paris. The study evaluated long-term safety and efficacy of denecimig prophylaxis in children, adolescents and adults with haemophilia A, with or without inhibitors.

This is relevant because haemophilia A remains a lifelong rare bleeding disorder where patients often need routine prophylaxis to prevent or reduce bleeding episodes. Treatment burden remains a major issue, particularly for patients who require frequent injections or have developed inhibitors that limit the effectiveness of factor replacement therapy.

Denecimig is an investigational bispecific antibody Factor VIIIa mimetic. It is designed to bridge Factor IXa and Factor X, mimicking the function of Factor VIIIa and helping restore thrombin generation capacity so the body can form clots more effectively.

The therapy is administered subcutaneously and is being studied across multiple dosing frequencies, including once weekly, once every two weeks and once monthly. This dosing flexibility could be commercially and clinically relevant because patients with haemophilia have different needs depending on age, lifestyle, disease severity, inhibitor status and treatment history.

The interim FRONTIER4 analysis included 426 people with haemophilia A aged one year and older who continued denecimig treatment after participating in earlier FRONTIER studies. The analysis included 365 adults and adolescents, with a median observation period of 0.50 years, and 61 children, with a median observation period of 0.33 years.

For safety, denecimig remained consistent with earlier findings from the FRONTIER programme. Injection-site reactions were reported at low rates, at 2.0 per cent of injections in children and 1.8 per cent in adolescents and adults. All injection-site reactions were mild and transient. No clinical evidence of neutralising antibodies was observed.

For efficacy, estimated mean annualised bleeding rates remained low across dosing schedules and inhibitor status. The estimated annualised bleeding rate was 0.75 for adults and adolescents, and 0.37 for children. Across all doses, approximately 71 per cent of adults and adolescents and 89 per cent of children experienced zero treated bleeds while receiving denecimig.

The extension study also evaluated patient-reported outcomes. Findings from prior FRONTIER studies were maintained over time, including improved joint pain among people aged 12 and older and reduced treatment burden among participants aged one year and older. Among 185 participants, 94.1 per cent found the denecimig pen-injector easy or very easy to use, while 89.7 per cent found it quick or very quick to prepare and inject.

The therapy remains investigational. Novo Nordisk submitted denecimig for review to the U.S. FDA through a Biologics License Application in September 2025.

The data strengthen Novo Nordisk’s position in haemophilia, where the company is also presenting paediatric Phase III explorer10 data for concizumab in children below 12 years of age with haemophilia A or B with inhibitors. In that trial, concizumab prophylaxis reduced annualised bleeding rate compared with previous on-demand treatment.