press release

Mim8 prophylaxis treatment shown to be well-tolerated when switching from emicizumab in people with haemophilia A in new phase 3 data presented at the ISTH 2025 Congress

- New FRONTIER5 data show that a direct switch to investigational Mim8 (denecimig) prophylaxis treatment from emicizumab, without the need for a washout period, was well-tolerated with no safety concerns in adults and adolescents with haemophilia A, with or without inhibitors[1].
- Switching to Mim8 led to a sustained increase in thrombin generation into the normal range, but without causing thrombin levels that might pose a thrombotic risk[1].
- FRONTIER5 Patient-Reported Outcomes (PROs) assessment found the Mim8 pen-injector easy to use, with strong user preference over their emicizumab injection system[2].
- These results add to the overall safety profile of Mim8 based on the FRONTIER clinical trial programme[3].

Bagsværd, Denmark, 22 June 2025 – Novo Nordisk today presented results from the phase 3b FRONTIER5 trial showing that a direct switch to investigational Mim8 (denecimig) prophylaxis from emicizumab treatment, without a washout period or Mim8 loading dose, was well-tolerated with no safety concerns in adults and adolescents living with haemophilia A, with or without inhibitors[1]. Additionally, a FRONTIER5 Patient-Reported Outcomes (PROs) assessment found the Mim8 pen-injector easy to use, with an overall strong user preference for the pen-injector compared to the previous emicizumab injection system[2,3]. The results were presented at the International Society on Thrombosis and Haemostasis (ISTH) Congress in Washington, D.C.

In the study, the first Mim8 maintenance dose was administered on the next planned emicizumab dosing day. Patients were given the option of switching to once-monthly, once every two weeks or once-weekly dosing frequencies of Mim8, regardless of their prior dosing frequency[1,3]. Steady-state Mim8 concentration was achieved by Week 16, and emicizumab elimination was completed by Week 26[1]. Switching to Mim8 led to a sustained increase in thrombin peak levels without an exaggerated thrombin response[1].

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CVR no: 24 25 67 90

VEEVA#: HQ25MiM00037 June - 2025

“Continuous prophylactic coverage is critical to avoiding breakthrough bleeds in people living with haemophilia; with new non-factor therapeutic options, many people could have hesitations about switching treatment options. These data demonstrate that switching to Mim8 from emicizumab can be done without requiring a washout period,” said Allison P. Wheeler, MD, Washington Center for Bleeding Disorders, Seattle, WA. “This is critical in ensuring that individuals maintain continuous protection against bleeding events as we seek to help address the ongoing needs of people living with this complex disease.”

The open-label phase 3b FRONTIER5 study consisted of 61 adults and adolescents, aged 12 years and older, with haemophilia A. Mim8 was well-tolerated with no safety concerns. No thromboembolic events, hypersensitivity reactions, or treatment-emergent adverse events (TEAEs) leading to discontinuation were observed, and there was no clinical evidence of neutralising anti-Mim8 antibodies[1].

The PROs data from FRONTIER5 indicated a strong overall preference for the Mim8 pen-injector, with 97% (n=57/59) of patients reporting a “very strong” or “fairly strong” preference in comparison to their previous emicizumab injection system[2]. Of the participants who completed the Haemophilia Device Handling and Preference Assessment (HDHPA) questionnaire at week 26, 98% (n=58/59) found the Mim8 pen-injector “very easy” or “easy” to use, and 95% (n=56/59) found it “much easier” or “easier” compared with their previous administration method. All participants (100%) were “extremely confident” or “very confident” in using the pen-injector correctly, and most participants (83%; n=49/59) found it “very easy” to inject the dose[2].

“The FRONTIER5 safety and patient-reported outcomes data support Mim8 as a potential future treatment option for people living with haemophilia A and demonstrate our continued commitment to developing innovative treatment options for this community”, said Stephanie Seremetis, chief medical officer and CVP for Haemophilia at Novo Nordisk. “These results give valuable insights into haemophilia A management, highlight the feasibility of directly switching to Mim8 from emicizumab, and reveal a strong patient preference for the Mim8 pen-injector device.”

Novo Nordisk expects to submit Mim8 for regulatory review during 2025. Data from the ongoing phase 3 FRONTIER programme will be disclosed at upcoming congresses and in publications in 2025 and 2026.

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[4]. It is estimated to affect approximately 1,125,000 people worldwide[5]. There are different types of haemophilia, which are characterised by the type of clotting factor protein that is defective or missing[4]. 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[4]. 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[6] that can cause replacement therapies to stop working.

About Mim8

Mim8 is an investigational FVIIIa mimetic bispecific antibody optimised with the aim to deliver improved potency and sustained efficacy across flexible dosing intervals up to once-monthly prophylaxis for people living with haemophilia A, with or without inhibitors[7-10]. Administered under the skin, Mim8 bridges Factor IXa and Factor X. This action replaces FVIII function, which helps restore the body's thrombin generation capacity into the normal range, helping blood to clot[7,11]. The use of Mim8 in people living with haemophilia A is investigational and not approved by regulatory authorities or available anywhere in the world.

About the FRONTIER5 trial

FRONTIER5 is a single-arm, open-label, 26-week, phase 3b trial evaluating the safety of switching from previous emicizumab prophylaxis treatment directly to Mim8 prophylaxis treatment using the Mim8 pen-injector in adults and adolescents with haemophilia A, with or without inhibitors[3].

The FRONTIER clinical programme investigates Mim8 as a prophylaxis treatment for people with haemophilia A, with or without inhibitors. This programme includes FRONTIER1, FRONTIER2, FRONTIER3, FRONTIER4 and FRONTIER5[3,12-15].

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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