press release

Mim8 phase 1 & 2 data demonstrates potential as once monthly treatment for people with haemophilia A

No thromboembolic events or related serious adverse events reported over 12-week observation period in FRONTIER1 study.[1]

London, UK, 11 July 2022 – Novo Nordisk announced that the phase 1 & 2 FRONTIER1 dose-escalation study in the treatment of people with haemophilia A met its primary safety endpoint.[1] Interim results for the safety, tolerability and activity of next-generation Factor VIIIa (FVIIIa) mimetic Mim8 at different dosages were presented today at the International Society of Thrombosis and Haemostasis Annual Congress (ISTH 2022) in London, UK.

In the FRONTIER1 study, once-weekly and once-monthly under the skin administration of Mim8 in people with haemophilia A was tolerated at all doses, regardless of inhibitor status.[1] While six of seven participants in the lowest dose cohort still reported at least one bleed, at higher doses (in dose cohorts two to four) only two of the 25 patients reported bleeds. Zero bleeds were reported in the eight participants treated with the therapy once monthly.[1]

“Mim8 demonstrated clinical proof-of-concept and no safety signals or signs of exaggerated coagulation were seen, which supports the further clinical development of Mim8 in people living with haemophilia A in phase 3 clinical trials,” said principal investigator Prof Jerzy Windyga, MD, Department of Hemostasis Disorders and Internal Medicine, Institute of Hematology and Transfusion Medicine, Warsaw, Poland. “We are encouraged by the first phase 1 & 2 data from FRONTIER1.”

No thromboembolic events (blood clots in the veins) or related serious adverse events were reported in the FRONTIER1 study, and there were no occurrences of the development of anti-Mim8 antibodies.[1]

“We are committed to investigating novel approaches to address the individual and changing needs for people living with haemophilia,” said Martin Lange, executive vice president and head of Development at Novo Nordisk. “The data for Mim8 thus far present an opportunity to develop a treatment for people with haemophilia A who may benefit from less frequent administration. We look forward to moving into next steps with this investigational therapy.”

The FRONTIER clinical development programme is using a novel and accelerated design to minimise time from phase 2 into phase 3. Dosing in the phase 3 study is expected to start in the fourth quarter of 2022.

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About the FRONTIER1 trial

FRONTIER1 is a phase 1 & 2 open-label study investigating the safety, tolerability, pharmacokinetics (presence of the drug in the body over a period of time), and pharmacodynamics (effects of the drug in the body) of Mim8 administered under the skin in 48 healthy participants (phase 1) and 42 participants with severe haemophilia A, independent of FVIII inhibitor status (phase 2).[1,2] Participants received Mim8 once weekly at different dose levels to target drug plasma levels of either 1µg/ml, 3µg/ml, 9µg/ml or 20µg/ml, or once monthly targeting plasma levels of 9µg/ml. The treatment regimen was continued over 12 weeks and participants continued on the same treatment regimen into the extension phase thereafter.[2] Data presented at the congress is from the 32 participants in dose cohorts one to four.

About haemophilia

Haemophilia is a rare disease that impairs the body's ability to make blood clots, a process needed to stop bleeding after a traumatic event. It is estimated to affect approximately 1,125,000 people worldwide.[3] Haemophilia A and B are more common in males than in females, with ~ 88% of people diagnosed with haemophilia worldwide being male.[4,5] Some people with haemophilia may also develop inhibitors, which are an immune system response to the clotting factors in replacement therapy that cause treatment to stop working. Currently, it is estimated that up to 30% of people living with haemophilia A have inhibitors.[6]

About Mim8

Mim8 is a next-generation human IgG4 bispecific antibody bridging Factor IXa/X (FIXa/FX) designed to be a potent once weekly or once monthly prophylaxis therapy for people living with haemophilia A with or without inhibitors[7]. It works by acting like a bridge, bringing FIXa and FX together thereby replacing missing FVIII, which in turn stimulates production of thrombin that helps blood to clot. The use of Mim8 in people with haemophilia A is investigational and not approved by regulatory authorities. It is currently being investigated in phase 1 & 2 clinical studies.

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 diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 49,300 people in 80 countries and markets its products in around 170 countries. 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, Facebook, Twitter, LinkedIn and YouTube.

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