company announcement

Novo Nordisk pauses the clinical trials investigating concizumab (anti-TFPI mAB) in haemophilia A and B with or without inhibitors

Bagsværd, Denmark, 16 March 2020 - Novo Nordisk today announced that two clinical trials in the concizumab phase 3 programme (explorer7 and 8) and one clinical trial in the phase 2 programme (explorer5) have been paused. The three clinical trials were investigating concizumab prophylaxis treatment in haemophilia A and B patients regardless of inhibitor status. Consequently, no additional patients will be recruited, and further treatment of patients currently enrolled in the trials with concizumab will cease.

The decision is a result of the occurrence of non-fatal thrombotic events in three patients enrolled in the ongoing phase 3 programme. Novo Nordisk and an independent Data Monitoring Committee are currently assessing the relevance of the events to the continuation of the programme and no conclusions have yet been made.

"While it is disappointing to pause the trials, patient safety is of utmost importance to Novo Nordisk – both for those taking part in our clinical trials and those who use our products on a daily basis" said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "Together with relevant authorities, we will now carefully evaluate all available data and decide how to best move forward".

About the concizumab phase 2 and 3 programmes
In October 2019, Novo Nordisk initiated the explorer7 phase 3 clinical trial with concizumab in patients with haemophilia A or B with inhibitors towards FVIII or FIX. The objective of the trial was to establish the safety and efficacy of once-daily prophylactic subcutaneous concizumab delivered in a pen device to reduce the number of bleeds. A parallel phase 3 trial in haemophilia A or B patients without inhibitors, explorer8, was initiated in November 2019. The trials were to enrol approximately 293 patients from 32 countries. The explorer5 phase 2 trial was initiated in October 2017 to evaluate the efficacy and safety of once-daily prophylactic subcutaneous concizumab delivered in a pen device to reduce the number of bleeds of haemophilia A patients. The trial currently includes 15 patients. Approximately 109 patients are currently being treated with concizumab.

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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 42,700 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, YouTube.

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