

# press release

## **Novo Nordisk resumes the phase 3 clinical trials investigating concizumab (anti-TFPI mAB) in haemophilia A and B with or without inhibitors**

**Bagsværd, Denmark, 13 August** – Novo Nordisk today announced that the clinical trials in the concizumab phase 3 programme (explorer6, 7 and 8) are being resumed. The clinical trials are investigating subcutaneous concizumab prophylaxis treatment in haemophilia A and B patients regardless of inhibitor status. This follows pausing of the trials in March 2020 due to the occurrence of non-fatal thrombotic events in three patients enrolled in the ongoing phase 3 programme.

Novo Nordisk has together with relevant authorities identified a new path forward for concizumab. New safety measures and guidelines, based on analysis of all available data, have been agreed with the FDA and the clinical hold has been lifted.

“I am pleased that we are able to safely restart the explorer trials. This emphasizes Novo Nordisk’s long-term dedication to the haemophilia community and our commitment to develop new subcutaneous prophylaxis options for all haemophilia patients,” said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk.

The trials will be resumed as soon as local procedures allow.

### **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 is 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 are to enrol approximately 293 patients from 32 countries. The trials were paused in March 2020.

*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 43,500 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.com](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).*

## **Further information**

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