NovoEight® maintains potency when stored at 40ºC offering people with haemophilia A increased flexibility in their daily lives

**Glasgow, UK, 21 May 2018** – A new long term stability study has shown that haemophilia A treatment NovoEight® (turoctocog alfa) remains potent after three months exposure to temperatures of 40ºC. The results were presented today at the WFH 2018 World Congress in Glasgow, UK.

Treatment storage issues, especially the need for refrigeration, have been shown to be a common problem reported by people with haemophilia A. A portability study recently published in *Patient Preference and Adherence* found that most people are restricted in their personal activities, particularly travel and sports, due to temperature storage issues. If efficacy and safety are unaffected, storage flexibility was shown to be a strong driver of product choice.

"Establishing the stability of NovoEight® up to 40ºC is part of our commitment to helping people with haemophilia A to reduce the burden that this condition places on their lives," said Mads Krogsgaard Thomsen, executive vice president and chief science officer, Novo Nordisk. "The recent data demonstrate the reliable nature of NovoEight® as a portable and convenient treatment option, which could help patients enjoy their daily lives without concern about the storage of their treatment."

The storage conditions for NovoEight® allows for it to be kept at temperatures of up to 40ºC for three months.

**About the study**

This was a long-term stability study comparing the potency of NovoEight® stored at 5ºC for 30 months to NovoEight® stored at 5ºC for 27 months, then followed by storage at 40ºC ±2ºC/75% relative humidity (RH) ±5% RH for three months. The potency of NovoEight® was maintained at high storage temperature and humidity conditions.

The effect of repeated temperature changes was tested by storage at 5ºC ±3ºC/ambient humidity/darkness for 24 months, followed by cycling between 5ºC and 40ºC/75% RH up to 10 times; the product was then stored at 40ºC/75% RH for three months (resulting in a total of four months at 40ºC), and returned to 5ºC to attain 30 months shelf life.
The potency of NovoEight® was maintained at high storage temperature and humidity conditions. Up to 10 cycles of temperature changes and storage at 40°C did not affect potency.¹

**About NovoEight®**

NovoEight® is a B-domain truncated recombinant human coagulation factor VIII for the treatment and prevention of bleeding in patients with haemophilia A.³

**About haemophilia A**

Haemophilia is a chronic, inherited bleeding disorder that primarily affects males. People with haemophilia A are either missing or have a malfunctioning factor VIII protein, which is needed for proper blood clotting. People with haemophilia A have a tendency to bleed longer than most or to bleed internally into joints, muscles or organs because they are missing this clotting factor. To manage the disease and stop bleeding, people with haemophilia A must replace the missing factor VIII protein, which is accomplished by intravenous injection of the clotting factor.⁴

Globally, it is estimated that 150,000 people have been diagnosed with haemophilia A.⁵ The disease is severely underdiagnosed in developing countries.

**About Novo Nordisk**

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 42,700 people in 79 countries and markets its products in more than 170 countries. For more information, visit [novonordisk.com](http://novonordisk.com), Facebook, Twitter, LinkedIn, YouTube.

**Further information**

**Media:**
Katrine Sperling  +45 4442 6718  krsp@novonordisk.com  
Åsa Josefsson  +45 3079 7078  aajf@novonordisk.com  

**Investors:**
Peter Hugrøffe Ankersen  +45 3075 9085  phak@novonordisk.com  
Anders Mikkelsen  +45 3079 4461  armk@novonordisk.com  
Christina Kjær  +45 3079 3009  cnje@novonordisk.com
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3. NovoEight® Summary of Product Characteristics, April 2018