



Company Announcement

28 September 2012

Novo Nordisk discontinues development of vatreptacog alfa following analysis of phase 3 results

Novo Nordisk today announced the decision to discontinue the development of vatreptacog alfa, a fast-acting recombinant factor VIIa analogue for haemophilia patients with inhibitors. The decision follows analysis of the data from the phase 3a trial adept™ 2. On 9 August, Novo Nordisk announced that a few patients in the trial had developed anti-drug antibodies to vatreptacog alfa, one patient with a potentially neutralising effect.

In the blinded adept™2 trial, 72 haemophilia patients with inhibitors were treated. Patients were treated on demand with either vatreptacog alfa or NovoSeven® in random sequence as bleedings occurred. In total, 567 bleeding episodes were treated.

The trial demonstrated that both vatreptacog alfa and NovoSeven® can stop a very high percentage of bleeding episodes, 93%, with three doses or less. However, a few patients developed anti-drug antibodies to vatreptacog alfa, including one patient with a potentially neutralising effect in one sample. Some of these patients also developed cross-binding antibodies to NovoSeven®. None of the antibodies were inhibitory and the patients responded well to treatment during the course of the trial.

In contrast to the findings for vatreptacog alfa, anti-drug antibodies have not previously been reported for NovoSeven® when used for haemophilia patients with inhibitors to factor VIII and IX. Consequently, the observation of anti-drug antibodies and the potential risks hereof for haemophilia patients with inhibitors has led Novo Nordisk to discontinue further development of vatreptacog alfa.

About vatreptacog alfa and adept™ 2

Vatreptacog alfa is a fast-acting recombinant FVIIa analogue discovered and developed by Novo Nordisk. Vatreptacog alfa was intended as an improved bypassing agent providing safe, rapid and sustained resolution of bleeds in patients with haemophilia and inhibitors. Structurally, three amino acid substitutions have been made to vatreptacog alfa compared with native FVIIa, to enhance platelet-dependent enzymatic activity, which makes vatreptacog alfa more than 99% homologous with native FVIIa.

Adept™2 is the largest double-blinded, randomised, controlled trial ever conducted with bypassing agents in haemophilia patients with inhibitors to FVIII or FIX. The trial was a global trial with participating haemophilia treatment centres from Africa, Asia, Europe, North and South America.

Novo Nordisk is a global healthcare company with 89 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 33,300 employees in 75 countries, and markets its products in more than 190 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

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