Press Release

7 December 2010

Novo Nordisk presents positive clinical data on two investigational compounds within bleeding disorders

New data presented at American Society of Hematology annual meeting highlight promising treatments that may help patients with bleeding disorders to better manage their condition than today.

Orlando, US – Novo Nordisk presented data from a phase 2 trial evaluating the safety, pharmacokinetics and efficacy of a recombinant factor VIIa (rFVIIa) analogue, designed to have a faster action profile than NovoSeven® (rFVIIa) in haemophilia patients with inhibitors (antibody formation against factor preparations). The company also presented data from a phase 3 trial investigating a recombinant compound in patients with congenital factor XIII deficiency, a rare, inherited bleeding disorder. The data were presented at the 52nd American Society of Hematology (ASH) Annual Meeting and Exposition.

rFVIIa analogue (NN1731)[1]: phase 2 results

Results were presented from a phase 2 trial, adept™1, in which haemophilia patients aged 12 years or older experiencing a joint bleed were randomised to receive up to three doses of NN1731 or NovoSeven®. The trial showed that NN1731 was safe and no antibody formation against NN1731 was seen in the trial. Evaluation of patients who received NN1731at the two highest dose levels showed that 96% of the joint bleeds were well-controlled with the product; the efficacy of NovoSeven® was similar to that observed in previous clinical studies (efficacy in approximately 90% of bleeds).

In addition, the number of adverse events (AEs), including serious adverse events (SAEs), was lower in patients being treated with NN1731 compared to

Novo Nordisk A/S
Corporate Communications

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888
Telefax:
+45 4444 2314

Internet:
novonordisk.com

CVR no:
24256790

those in the control group. A total of 12 SAEs were reported and all occurred 16 days or longer after exposure to NN1731.

"There were no safety concerns observed in patients at any dose level of NN1731," said Dr Erich de Paula, of the State University of Campinas in São Paulo, Brazil, who presented the trial during the meeting. "Additionally, the phase 2 trial results demonstrated the potential of the rFVIIa analogue to stop joint bleeds quickly and effectively. These results further support the distinct fast action profile of the rFVIIa analogue in treating bleeds in haemophilia patients with inhibitors."

NovoSeven® was used as a control in the trial due to its proven efficacy and safety profile. NovoSeven® was specifically developed to treat people with haemophilia A or B with inhibitors to factor VIII or IX replacement.

rFXIII compound: phase 3 results

Results were presented from mentor™1[2], a phase 3 trial examining the efficacy and safety of a recombinant factor XIII (rFXIII) compound for the prevention of bleeds associated with congenital FXIII deficiency, a rare bleeding disorder with about 600–1,000 diagnosed patients worldwide.

In the trial, 41 patients were treated for one year, with rFXIII administered as a preventative, once-monthly replacement therapy for congenital FXIII deficiency. FXIII-deficient patients with no previous history of FXIII treatment were used as a control. Currently, the only treatment available is derived from human blood plasma, which carries an inherent risk of infections.[3]

The trial results demonstrated that treatment with monthly recombinant FXIII injections significantly decreased the number of bleeding episodes requiring treatment compared to the historic control group. Over the course of the treatment period, a total of five bleeding episodes were observed in four patients. All five events were associated with trauma, and were not related to low FXIII activity levels in patients. Additionally, no thromboembolic events or fatal adverse events were reported.

"These data show the potential for rFXIII to become a safe and effective treatment option for patients who would otherwise use treatments at risk for contamination," said Prof Aida Inbal of the Hemostasis Unit and Hematology Clinic in the Institute of Hematology at Rabin Medical Center in Tel Aviv, Israel. "We think this is an extremely important milestone in the development of a treatment that is not sourced from human plasma for patients suffering from congenital FXIII deficiency."

Novo Nordisk A/S
Corporate Communications

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888
Telefax:
+45 4444 2314

Internet:
novonordisk.com

CVR no:
24256790

Novo Nordisk plans to file for US Food and Drug Administration approval of the rFXIII in the first half of 2011.

About congenital haemophilia

Congenital haemophilia, which is typically diagnosed in childhood, is a chronic, inherited bleeding disorder that occurs when certain blood clotting factors are missing or do not work properly, resulting in easy bruising and prolonged bleeding which can occur spontaneously, or after trauma. Neutralising antibodies known as inhibitors, a serious complication that can occur after treatment, develop in as many as 30% of those with haemophilia[4]. In these patients, antibodies form that neutralise the blood coagulation factors VIII or IX contained in the replacement therapy. Bleeding episodes in patients with inhibitors can be more difficult to manage, potentially resulting in long-term poorer outcomes, such as joint disease.[5]

About congenital FXIII deficiency

Patients with congenital FXIII deficiency have a lifelong increased risk of all types of bleeding episodes. The incidence of congenital FXIII deficiency is approximately one case per 2 million people,[6] with an estimated 600−1,000 diagnosed patients worldwide.

Headquartered in Denmark, Novo Nordisk is a global healthcare company with 87 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. For more information, visit novonordisk.com.

Novo Nordisk A/S
Corporate Communications

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888
Telefax:
+45 4444 2314

Internet:
novonordisk.com

CVR no:
24256790

Further information:

Media:

Outside North America:
Rachel Curtis Gravesen
Tel: (+45) 4442 7603
rcgv@novonordisk.com

In North America:
Ambre Morley
Tel: (+1) 609 987 5898
abmo@novonordisk.com

Investors:

Outside North America:
Klaus Bülow Davidsen
Tel: (+45) 4442 3176
klda@novonordisk.com

Kasper Roseeuw Poulsen
Tel: (+45) 4442 4471
krop@novonordisk.com

Jannick Lindegaard
Tel: (+45) 4442 4765
jlis@novonordisk.com

In North America:
Hans Rommer
Tel: (+1) 609 919 7937
hrmm@novonordisk.com

---

[1] de Paula, E. et al. Safety and Preliminary Efficacy of Recombinant Activated FVII Analog (NN1731) in the Treatment of Joint Bleeds in Congenital Hemophilia Patients with Inhibitors [abstract]. Available at: http://ash.confex.com/ash/2010/webprogram/Paper31391.html. Accessed November 16, 2010.

[2] Inbal, A. et al. Recombinant Factor XIII, Safe and Novel Treatment for Congenital Factor XIII Deficiency [abstract]. Available at: http://ash.confex.com/ash/2010/webprogram/Paper31589.html. Accessed November 16, 2010.

[3] Acharya SS, *et al.* North American Rare Bleeding Disorder Study Group, Rare Bleeding Disorder Registry: deficiencies of factor II, V, VII, X, XIII, fibrinogen and dysfibrinogenemias. *J Thromb Haemost* 2004; 2: 248–56.

[4] Colowick A, Bohn R, Avorn J et al. Immune tolerance induction in hemophilia patients with inhibitors: costly can be cheaper. *Blood.* 2000;96(5): 1698-1702.

[5] Brown, M. et al. (2009) "Health Related Quality of Life of Hemophilia Patients with Inhibitors." Hemophilia. 2009 Jul;15(4):911-7. Epub 2009 Apr 9.

[6] Peyvandi F, et al. Rare bleeding disorders. Haemophilia 2006; 12(Suppl 3): 137–42.

Novo Nordisk A/S
Corporate Communications

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888
Telefax:
+45 4444 2314

Internet:
novonordisk.com

CVR no:
24256790