European Medicines Agency
Press office

London, 06 April 2006
Doc. Ref. EMEA/123938/2006

Press release
Novo Nordisk withdraw their application to extend the marketing authorisation for NovoSeven

The European Medicines Agency was formally notified by Novo Nordisk A/S of their decision to withdraw the application for an extension of the marketing authorisation for the medicinal product NovoSeven (Human recombinant coagulation Factor VIIa (rFVIIa)).

NovoSeven was first authorised in the European Union on 23 February 1996 and is currently indicated for the treatment of bleeding episodes and prevention of bleeding during surgery or invasive procedures in specific patients with certain blood-clotting disorders.
On 6 October 2005, Novo Nordisk A/S submitted an application for the extension of the marketing authorisation to include the treatment of acute intracerebral haemorrhage in adults for limiting haemorrhage growth and improving clinical outcomes.

Following review of the data submitted, the Committee for Medicinal Products for Human Use (CHMP) requested the company to submit additional safety and efficacy data. In their official withdrawal letter, the company stated that based on this request they decided to withdraw the current application and re-submit an application upon completion of an ongoing clinical study.

More information about NovoSeven and the current state of the scientific assessment at the time of withdrawal will be made available in a question and answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website, after the next meeting of the Committee for Medicinal Products for Human Use (CHMP) on 24-27 April 2006.

--ENDS--

NOTES

1. The legal basis for the publication of this withdrawal are Articles 11 and 80 of Regulation (EC) No 726/2004.
2. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
3. More information about NovoSeven is available in the European Public Assessment Report (EPAR): http://www.emea.eu.int/humandocs/Humans/EPAR/novoseven/novoseven.htm.
4. NovoSeven is currently indicated for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups: in patients with congenital haemophilia with inhibitors to coagulation factors VIII or IX > 5 BU; in patients with congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration; in patients with acquired haemophilia; in patients with congenital FVII deficiency; in patients with Glanzmann's thrombasthenia with antibodies to GP IIb-IIIa and/or HLA, and with past or present refractoriness to platelet transfusions.
5. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int

Media enquiries only to:
Martin Harvey Allchurch
Tel: (44-20) 74 18 84 27, E-mail: press@emea.eu.int