European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom
Attn.: Dr. Daniel Brasseur, Chairman of the CHMP

03 April 2006

Subject: Withdrawal of NovoSeven® EU/1/96/006/001-003 application For Type II Variation, EMEA/H/C/0074/II Additional Indication for NovoSeven to Comprise the Use in Patients with Acute Intracerebral Haemorrhage (ICH), 1.2mg, 2.4mg and 4.8mg

Dear Dr. Daniel Brasseur,

I would like to inform you that, at this point of time, Novo Nordisk A/S has taken the decision to withdraw the NovoSeven® EU/1/96/006/001-003 application for Type II Variation, EMEA/H/C/0074/II Additional Indication for NovoSeven to comprise the following wording:
"NovoSeven is a haemostatic agent indicated for the treatment of acute intracerebral haemorrhage (ICH) in adults for limiting haemorrhage growth and improving clinical outcome.

The withdrawal is based on the following reasons:
Novo Nordisk has received feedback from EMEA, indicating a need for receiving additional efficacy and safety data prior to granting an approval. Based on this Novo Nordisk will withdraw the current file and resubmit an application upon completion of the phase 3 study. The withdrawal has no consequences for the ongoing phase 3 study which is recruiting at a higher than expected rate.

I agree for this letter to be published on the EMEA website.

Yours sincerely,

Global Regulatory Affairs Project Director

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