24 May 2012
EMA/CHMP/246097/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Novothirteen

Catridecacog

On 24 May 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Novothirteen, 2500 IU, Powder and solvent for solution for injection intended for long term prophylactic treatment of bleeding in patients 6 years and above with congenital factor XIII A-subunit deficiency. Novothirteen was designated as an orphan medicinal product on 12 December 2003. The applicant for this medicinal product is Novo Nordisk A/S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Novothirteen is Catridecacog, a recombinant coagulation factor XIII A-subunit from the therapeutic class of antihaemorrhagics blood coagulation factor XIII (ATC code: B02BD11) produced in yeast cells by recombinant DNA technology. It is structurally identical to the human FXIII A-subunit [A2], the subunit of FXIII which contains the enzymatic activity, which binds to the FXIII B-subunit [A_2B_2]. Upon activation, FXIII cross-links fibrin and other proteins resulting in increased mechanical strength and resistance to fibrinolysis of the fibrin clot and contributes to enhanced platelet and clot adhesion to the injured tissue.

The benefits with NovoThirteen are its ability to substitute the endogenous FXIII A-subunit [A2] in congenital factor XIII A-subunit deficient patients and decreasing the rate of bleeding episodes requiring treatment with a FXIII-containing product as compared to historical controls. The most common side effects are headache, leucopenia and aggravated neutropenia, pain in extremity, injection site pain, non-neutralising antibodies and fibrin D-dimer increase.

A pharmacovigilance plan for Novothirteen will be implemented as part of the marketing authorisation.

The approved indication is: " Long term prophylactic treatment of bleeding in patients 6 years and above with congenital factor XIII A-subunit deficiency.. It is proposed that Novothirteen should be prescribed and initiated under the supervision of a physician experienced in the treatment of rare bleeding disorders.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Novothirteen and therefore recommends the granting of the marketing authorisation.