European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 20 November 2008
Doc.Ref. EMEA/CHMP/571877/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
NPLATE

International Nonproprietary Name (INN): ***romiplostim***

On 20 November 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Nplate, 250 µg, 500 µg, powder for solution for injection intended for the treatment of adult chronic immune (idiopathic) thrombocytopenic purpura (ITP).

Nplate was designated as an orphan medicinal product on 27 May 2005. The applicant for this medicinal product is Amgen Europe B.V.

The active substance of Nplate is romiplostim, an antihaemorragic medicinal product (ATC code not yet assigned) that increases platelet production. Nplate is an Fc-peptide fusion protein that activates intracellular transcriptional pathways via the thrombopoietin (TPO) receptor.

The benefits with Nplate have been shown in two phase III, placebo-controlled, double-blind studies in adults with ITP. In both studies, efficacy has been shown in terms of a durable platelet response compared to patients receiving placebo. The most common side effects are headache, fatigue, arthralgia, myalgia, injection site bruising, injection site pain, oedema peripheral, dizziness, muscle spasms, nausea, contusion, diarrhoea, bone marrow disorder, influenza like illness, insomnia and pruritus.

A pharmacovigilance plan for Nplate, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Nplate is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Nplate may be considered as second line treatment for adult non-splenectomised patients where surgery is contra-indicated."
It is proposed that Nplate treatment should remain under the supervision of a physician who is experienced in the treatment of haematological diseases.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be 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 that there is a favourable benefit to risk balance for Nplate and therefore recommends the granting of the marketing authorisation.

---

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu