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

London, 25 July 2008
Doc.Ref.: EMEA/CHMP/360673/2008

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

International Non-proprietary Name (INN): ***filgrastim***

On 24 July 2008, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive revised opinion, recommending to grant a marketing authorisation for the medicinal product Tevagrastim, solution for injection or infusion (30 MIU/0.5 ml and 48 MIU/0.8 ml) in a pre-filled syringe intended for the treatment of neutropenia. The Applicant for this medicinal product is Teva Generics GmbH.

The active substance of Tevagrastim is filgrastim, an immunostimulating medicinal product (L03AA02) which regulates the production and release of functional neutrophils from the bone marrow.

Tevagrastim is a biological medicinal product similar to the reference product Neupogen authorised in the EU. Studies have shown Tevagrastim to have a comparable quality, safety and efficacy profile to Neupogen (filgrastim).

The most common side effects are bone pain, diarrhoea, asthenia, myalgia, arthralgia, headache and pyrexia.

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

The approved indications are:

> Tevagrastim is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.
>
> Tevagrastim is indicated for the mobilisation of peripheral blood progenitor cells (PBPC).
>
> In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 x 10^9/l, and a history of severe or recurrent infections, long term administration of Tevagrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.
>
> Tevagrastim is indicated for the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

* 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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Filgrastim therapy should only be given in collaboration with an oncology centre which has experience in granulocyte-colony stimulating factor (G-CSF) treatment and haematology and has the necessary diagnostic facilities. The mobilisation and aphaeresis procedures should be performed in collaboration with an oncology-haematology centre with acceptable experience in this field and where the monitoring of haematopoietic progenitor cells can be correctly performed.

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 Tevagrastim and therefore recommends the granting of the marketing authorisation.