European Medicines Agency
Evaluation of Medicines for Human Use

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION[*]
for
REVOLADE

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

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,[**] recommending granting a marketing authorisation for the medicinal product Revolade, 25 mg and 50 mg, film coated tablets intended for the treatment of adult chronic immune (idiopathic) thrombocytopenic purpura (ITP).

Revolade was designated as an orphan medicinal product on 03 August 2007. The applicant for this medicinal product is GlaxoSmithKline Trading Services Ltd.

The active substance of Revolade is eltrombopag olamine, an antihemorrhagic medicinal product (ATC Code B02BX05) that increases platelet production. Revolade is a small molecule that activates intracellular transcriptional pathways via the thrombopoietin (TPO) receptor.

The benefits with Revolade 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, nausea, alanineaminotransferase increased, aminotransferase increased, diarrhoea, fatigue, paraesthesia, constipation, rash, pruritus, blood bilirubin increased, cataract, arthralgia, myalgia and hyperbilirubinaemia.

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

The approved indication is: 'Revolade is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade may be considered as second line treatment for adult non-splenectomised patients where surgery is contraindicated'.
It is proposed that Revolade 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 Revolade 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.

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