16 December 2010
EMA/CHMP/820343/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Esbriet

pirfenidone

On 16 December 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Esbriet, hard capsules, 267 mg intended for treatment of idiopathic pulmonary fibrosis (IPF). Esbriet was designated as an orphan medicinal product on 16 November 2004. The applicant for this medicinal product is InterMune Europe Ltd. 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 in Esbriet is pirfenidone, an immunosuppressant (L04AX05). Its mechanism of action has not been fully established. However, existing data suggest that pirfenidone exerts both antifibrotic and anti-inflammatory properties.

The benefits with Esbriet are its ability to reduce the rate of deterioration of lung function measured as reduced decline of percent predicted Forced Vital Capacity (FVC) in patients with idiopathic pulmonary fibrosis. It is noted that demonstration of this effect in the clinical studies was modest but measureable. In addition, a trend in improvement of the “six minute walk test” was observed. The most common side effects are nausea, rash, fatigue, diarrhoea, dyspepsia and photosensitivity reaction.

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

The approved indication is: “Esbriet is indicated in adults for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF).” It is proposed that treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of IPF.

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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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