24 May 2012
EMA/293828/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Inlyta

(axitinib)

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 Inlyta, 1 mg and 5 mg film-coated tablets, intended for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. Inlyta was designated as an orphan medicinal product on 23 February 2011. The applicant for this medicinal product is Pfizer 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 of Inlyta is axitinib, a protein kinase inhibitor of vascular endothelial growth factor receptors (L01XE17) that inhibits VEGF-mediated endothelial cell proliferation and survival.

The benefits with Inlyta are its ability to delay the progression of disease in patients previously treated with sunitinib and its ability to improve the survival and to delay the progression of disease in patients previously treated with cytokines. The most common side effects are diarrhoea, hypertension, fatigue, dysphonia, nausea, decreased appetite, and palmar-plantar erythrodysaesthesia (hand-foot) syndrome.

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

The approved indication is: ‘‘Inlyta is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine”. It is proposed that Inlyta should be conducted by a physician experienced in the use of anticancer therapies.

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 Inlyta and therefore recommends the granting of the marketing authorisation.

[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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