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

London, 29 May 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
AFINITOR

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

On 29 May 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Afinitor, 10 mg, 5 mg, tablets intended for the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy. Afinitor was designated as an orphan medicinal product on 05 June 2007. The applicant for this medicinal product is Novartis Europharm Ltd.

The active substance of Afinitor is everolimus, an anti-neoplastic medicinal product (L01XE10) that inhibits the mTOR pathway, a protein kinase involved in regulating cell growth, proliferation, survival and the activation of vascular endothelial growth factor receptor, which is involved in angiogenesis.

The benefit with Afinitor is the prolongation of progression free survival by approximately 3 months for Afinitor-treated patients compared to placebo-treated patients. The most common side effects are stomatitis /mucositis, infections, cytopenias, rash and similar events, metabolic events, renal events, pulmonary events, bleeding and thromboembolic events, hepatic events. A pharmacovigilance plan for Afinitor, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Afinitor is intended for the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy. Treatment with Afinitor should be initiated and supervised 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 (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 Afinitor and therefore recommends the granting of the marketing authorisation.

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* 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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