22 April 2010
EMA/CHMP/104905/2010 Rev. 1
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Votrient

Pazopanib hydrochloride

On 22 April 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a revised positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Votrient, 200 and 400 mg for oral use, intended for the treatment of advanced renal cell carcinoma. The revision was triggered by the removal of pazopanib hydrochloride from the Community register of orphan medicinal products, on the applicant's request.

The applicant for this medicinal product is Glaxo Group Limited. 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 Votrient is pazopanib hydrochloride, an antineoplastic agent, protein kinase inhibitor (L01XE11) that inhibits multiple receptor tyrosine kinases (RTKs) that are implicated in angiogenesis, tumour growth and metastatic progression of cancer.

The benefits with Votrient have been shown in a phase III, randomised, double-blind, placebo-controlled multicentre study in patients with advanced renal cell carcinoma. In this study efficacy has been shown in terms of an increased progression free survival in patients receiving pazopanib compared to placebo. The most common side effects are diarrhoea, hair colour change, hypertension, nausea, fatigue, anorexia, vomiting, dysgeusia, elevated alanine aminotransferase and elevated aspartate aminotransferase and abdominal pain.

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

The approved indication is: "Votrient is indicated for the first line treatment of advanced Renal Cell Carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease". It is proposed that Votrient treatment should only be initiated by a physician experienced in the administration of anti-cancer agents.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Votrient and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.