



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 May 2012  
EMA/CHMP/225896/2012  
Committee for Medicinal Products for Human Use (CHMP)

## **Summary of opinion<sup>1</sup> (post authorisation)**

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### Votrient pazopanib

On 24 May 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product **Votrient**. The marketing authorisation holder for this medicinal product is Glaxo Group Ltd. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

#### “Soft tissue sarcoma (STS)

Votrient is indicated for the treatment of adult patients with selective subtypes of advanced Soft Tissue Sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy.

Efficacy and safety has only been established in certain STS histological tumour subtypes (see section 5.1)<sup>1</sup>”.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for **Votrient** will be as follows<sup>2</sup>:

#### Renal cell carcinoma (RCC)

Votrient is indicated in adults for the first line treatment of advanced Renal Cell Carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

<sup>2</sup> The text in bold represents the new or the amended indication.



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