



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2013
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Stivarga regorafenib

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Stivarga 40 mg film-coated tablet intended for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy. The applicant for this medicinal product is Bayer Pharma AG. 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 Stivarga is regorafenib, a protein kinase inhibitor (L01XE21) with activity against kinases involved in tumour angiogenesis (VEGFR1, -2, -3, TIE2), oncogenesis (KIT, RET, RAF-1, BRAF, BRAF^{V600E}), and the tumour microenvironment (PDGFR, FGFR).

The benefit with Stivarga is its ability to improve the survival of patients compared to placebo. The most common side effects are asthenia/fatigue, decreased appetite and food intake, hand foot skin reaction, diarrhoea, weight loss, infection, hypertension and dysphonia.

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

The approved indication is: "Stivarga is indicated for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy". It is proposed that Stivarga be prescribed by physicians experienced in the administration of anticancer therapy.

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.

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.



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