15 November 2012
EMA/CHMP/697268/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zaltrap

aflibercept

On 15 Novemebr 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 Zaltrap, 25 mg/ml, concentrate for solution for infusion, intended, in combination with irinotecan/ 5-fluorouracil/ folinic acid (FOLFIRI) chemotherapy, for the treatment of adults with metastatic colorectal cancer (MCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen. The applicant for this medicinal product is Sanofi-Aventis Groupe. 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 Zaltrap is aflibercept, an antineoplastic agent (ATC Code not yet assigned) acting as a decoy receptor of Vascular Endothelial Growth Factor (VEGF) thereby blocking the VEGF biological pathway. This pathway is important for the blood supply of tumours, although other biological functions of the pathway have been described.

The benefits with Zaltrap are its ability to improve the survival of patients and to delay the progression of disease compared to placebo. The most common side effects are leucopenia, diarrhoea, neutropenia, proteinuria, increased aspartate aminotransferase (AST), stomatitis, fatigue, thrombocytopenia, increased alanine aminotransferase (ALT), hypertension, weight loss, decreased appetite, epistaxis, abdominal pain, dysphonia, increased serum creatinine, and headache.

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

The approved indication is: "Zaltrap in combination with irinotecan/5 fluorouracil/folinic acid (FOLFIRI) chemotherapy is indicated in adults with metastatic colorectal cancer (MCRC) that is resistant to or has progressed after an oxaliplatin containing regimen". It is proposed that Zaltrap be prescribed by physicians experienced in the use of antineoplastic medicinal products.

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

[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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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 Zaltrap and therefore recommends the granting of the marketing authorisation.