19 May 2011
EMA/CHMP/384358/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Yervoy

ipilimumab

On 19 May 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yervoy, 5mg/ml concentrate for solution for infusion, intended for the treatment of advanced melanoma. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG. 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 Yervoy is ipilimumab, an antineoplastic agent monoclonal antibody (ATC code: L01XC11), which acts as a T-cell potentiator that specifically blocks the inhibitory signal of CTLA-4, resulting in T-cell activation, proliferation, and lymphocyte infiltration into tumours, leading to tumour cell death.

The benefits with Yervoy are its ability to increase overall survival in patients with advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. The most common side effects are diarrhoea, rash, pruritus, fatigue, nausea, vomiting, decreased appetite and abdominal pain.

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

The approved indication is: “Yervoy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy”. It is proposed that Yervoy is prescribed by physicians experienced in the treatment of cancer.

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.

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