28 April 2016
EMA/CHMP/268320/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zinbryta

daclizumab

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zinbryta, intended for the treatment of relapsing forms of multiple sclerosis. The applicant for this medicinal product is Biogen Idec Ltd. The Committee also concluded that the active substance contained in Zinbryta, daclizumab, could not be considered a new active substance.

Zinbryta will be available as a 150 mg solution for injection. The active substance, daclizumab, is a humanised IgG1 monoclonal antibody that binds to CD25 (IL-2Rα), and prevents interleukin-2 from binding to CD25 (ATC code: L04AC01).

The benefits with Zinbryta are its ability to reduce the annualised relapse rate (ARR), as well as the risk of 24-week confirmed disability progression. The most common side effects are elevations of liver enzymes and hepatic injury, cutaneous events, infections, gastrointestinal disorders and depression.

The full indication is: "Zinbryta is indicated in adult patients for the treatment of relapsing forms of multiple sclerosis (RMS)". It is proposed that Zinbryta be prescribed by physicians experienced in the management of multiple sclerosis.

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

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