



20 March 2014
EMA/CHMP/142794/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

SYLVANT SILTUXIMAB

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sylvant, 100 mg and 400 mg, Powder for concentrate for solution for infusion intended for the treatment of multicentric Castleman's disease (MCD). Sylvant was designated as an orphan medicinal product on 30 November 2007. The applicant for this medicinal product is Janssen-Cilag International NV. 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 Sylvant is siltuximab, a human-mouse chimeric monoclonal antibody that specifically binds to and neutralizes human IL-6 with high affinity.

The benefits with Sylvant are its ability to reduce the tumour burden and to improve the symptoms in MCD patients. The most common side effects are infections (including upper respiratory tract infections), pruritus, and maculopapular rash.

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

The approved indication is: "Sylvant is indicated for the treatment of adult patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative". It is proposed that Sylvant should be administered by qualified healthcare professionals and under appropriate medical supervision.

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.

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

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.

