



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of marketing authorisation

Sylvant (siltuximab) for the treatment of Castleman's disease

During its meeting of 8 to 9 April 2014, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/07/508 for Sylvant (siltuximab, previously known as chimeric-anti-interleukin 6 monoclonal antibody) as an orphan medicinal product for the treatment of Castleman's disease. The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other satisfactory methods of treatment. The COMP recommended that the orphan designation of the medicine be maintained¹.

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Sylvant for:

'the treatment of adult patients with multicentric Castleman's disease who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.'

This falls within the scope of the product's designated orphan indication, which is: 'treatment of Castleman's disease'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2007. Castleman's disease remains a seriously debilitating and life-threatening disease, especially when the disease affects more than one lymph node, because patients are at increased risk of infections, kidney failure and certain cancers.

Prevalence of the condition

The sponsor provided information on the prevalence of Castleman's disease from published data, which did not suggest a change in the prevalence of the condition since Sylvant's original orphan designation.

¹ The maintenance of the orphan designation at time of marketing authorisation would, except in specific situations, give an orphan medicinal product 10 years of market exclusivity in the EU. This means that in the 10 years after its authorisation similar products with a comparable therapeutic indication cannot be placed on the market.



On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of Castleman's disease remains below the ceiling for orphan designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the prevalence was estimated to be less than 1 person in 10,000. This is equivalent to fewer than 51,000 people in the EU.

Existence of other methods of treatment

The COMP noted that, at the time of the review of the orphan designation, no treatments were authorised in the EU for patients affected by Castleman's disease.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that Sylvant still meets the criteria for designation as an orphan medicinal product and that Sylvant should remain in the Community Register of Orphan Medicinal Products.

Further information on the current regulatory status of Sylvant can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports.