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

Bavencio (avelumab) for the treatment of Merkel cell carcinoma

On 25 July 2017, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/15/1590 for Bavencio (avelumab[1]) as an orphan medicinal product for the treatment of Merkel cell carcinoma. 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 methods of treatment. The COMP recommended that the orphan designation of the medicine be maintained[2].

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

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Bavencio for: 'treatment of adult patients with metastatic Merkel cell carcinoma'.

This falls within the scope of the product's designated orphan indication, which is: 'treatment of Merkel cell carcinoma'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2015. Merkel cell carcinoma remains a condition that is life threatening as it grows rapidly and spreads quickly to other parts of the body and once the cancer has spread, it is associated with very poor long-term survival.

Prevalence of the condition

The sponsor provided updated information on the prevalence of Merkel cell carcinoma based on data from the scientific literature.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of Merkel cell carcinoma 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

[1] Previously known as recombinant human monoclonal IgG1 antibody against programmed death ligand-1.
[2] 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 the same therapeutic indication cannot be placed on the market.

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prevalence was still estimated to be approximately 0.4 people in 10,000. This is equivalent to a total of fewer than 21,000 people in the EU.

Existence of other methods of treatment of Merkel cell carcinoma

The COMP noted that, at the time of the review of the orphan designation, no treatments were authorised in the EU for Merkel cell carcinoma.

Conclusions

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

More information on the COMP assessment can be found in the September 2017 COMP minutes.

Further information on Bavencio 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.