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Committee for Orphan Medicinal Products

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

Cresemba (isavuconazole) for the treatment of invasive aspergillosis

During its meeting of 1 to 3 September 2015, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/14/1284 for Cresemba (isavuconazole) as an orphan medicinal product for the treatment of invasive aspergillosis. 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. As other methods of treatment are authorised in the European Union (EU), the COMP also considered whether the medicine is of significant benefit to patients with invasive aspergillosis. The COMP recommended that the orphan designation of the medicine be maintained[1].

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

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Cresemba for the treatment of 'invasive aspergillosis'.

This falls within the scope of one of the product's designated orphan indications, which is: 'invasive aspergillosis'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2014. Invasive aspergillosis, a fungal infection, remains a condition that is life-threatening due to damage to the lungs and other organs.

Prevalence of the condition

The sponsor provided updated information on the prevalence of invasive aspergillosis based on data from the published literature.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of invasive aspergillosis remains below the ceiling for orphan

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the prevalence was still estimated to be less than 2 people in 10,000. This is equivalent to a total of fewer than 102,000 people in the EU.

Existence of other methods of treatment

At the time of the review of the orphan designation, other treatments were authorised in the EU for the treatment of invasive aspergillosis, with voriconazole being the primary treatment. Other medicines included posaconazole and amphotericin B.

Significant benefit of name of product

The COMP concluded that the claim of a significant benefit of Cresemba in invasive aspergillosis is justified on the basis of data showing improved safety of the medicine compared with other treatments, including reduced effects on the liver.

Therefore, although other methods for the treatment of this condition have been authorised in the EU, the COMP concluded that Cresemba is of significant benefit to patients affected by invasive aspergillosis.

Conclusions

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

Further information on the current regulatory status of Cresemba 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.