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EMA/COMP/766700/2014
Committee for Orphan Medicinal Products

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

Ofev (nintedanib) for the treatment of idiopathic pulmonary fibrosis

During its meeting of 9 to 11 December 2014, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/13/1123 for Ofev (nintedanib) as an orphan medicinal product for the treatment of idiopathic pulmonary fibrosis. 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 idiopathic pulmonary fibrosis. 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 Ofev for the treatment of idiopathic pulmonary fibrosis in adults.

This falls within the scope of the product's designated orphan indication, which is: 'treatment of idiopathic pulmonary fibrosis'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2013. Idiopathic pulmonary fibrosis remains a debilitating and life-threatening condition because the lungs gradually lose their ability to work properly.

Prevalence of the condition

The sponsor performed a search of the scientific literature and concluded that no publications are available which suggest a change in prevalence of idiopathic pulmonary fibrosis.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of idiopathic pulmonary fibrosis 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.

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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 not more than 3 people in 10,000. This is equivalent to a total of not more than 153,000 people in the EU.

Existence of other methods of treatment

At the time of the review of the orphan designation, Esbriet (pirfenidone) was the only medicine authorised in the EU to treat mild to moderate idiopathic pulmonary fibrosis.

Significant benefit of Ofev

The COMP concluded that the claim of a significant benefit of Ofev in idiopathic pulmonary fibrosis is justified because Ofev can also be used to treat those patients with disease severity other than mild to moderate, for whom no treatment is authorised.

Therefore, although other methods for the treatment of this condition have been authorised in the EU, the COMP concluded that Ofev is of significant benefit to patients affected by idiopathic pulmonary fibrosis.

Conclusions

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

Further information on the current regulatory status of Ofev 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