25 September 2012
EMA/COMP/452266/2012
Committee for Orphan Medicinal Products

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

Revestive (teduglutide) for the treatment of short bowel syndrome

During its meeting of 10-11 July 2012, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/01/077 for Revestive (teduglutide)[1] as an orphan medicinal product for the treatment of short bowel syndrome. 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 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 Revestive for:

'treatment of adult patients with short bowel syndrome. Patients should be stable following a period of intestinal adaptation after surgery'.

This falls within the scope of the product's designated orphan indication, which is: 'treatment of short bowel syndrome'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2001. Short bowel syndrome remains a condition that is serious, debilitating in the long term and, in many cases, life threatening, particularly because it may lead to severe malnutrition, generalised infections or metabolic problems, as well as liver failure.

Prevalence of the condition

The sponsor provided estimates on the prevalence of short bowel syndrome from the scientific literature and data from a registry in Sweden.

[1] At time of orphan designation teduglutide was known as [gly2]-recombinant human glucagon-like peptide.
[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 a comparable therapeutic indication cannot be placed on the market.

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On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of short bowel syndrome 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 0.44 people in 10,000. This is equivalent to a total of fewer than 22,300 people in the EU.

Existence of other satisfactory methods of treatment

The COMP noted that, at the time of the review of the orphan designation, no medicinal products were authorised in the EU for patients with short bowel syndrome. Treatments aimed at relieving the symptoms of the condition, including dietary measures and parenteral nutrition, and were not considered satisfactory.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that Revestive 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 Revestive 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.