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Committee for Orphan Medicinal Products

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

SomaKit TOC (edotreotide) for the diagnosis of gastroenteropancreatic neuroendocrine tumours

On 14 October 2016, the Committee for Orphan Medicinal Products (COMP) completed a review of the designation EU/3/15/1450 for SomaKit TOC (edotreotide, for use after radiolabelling as gallium (^{68}Ga)-edotreotide) as an orphan medicinal product for the diagnosis of gastroenteropancreatic neuroendocrine tumours (GEP-NET). 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 diagnosis. As other methods of diagnosis are authorised in the European Union (EU), the COMP also considered whether the medicine is of significant benefit to patients with GEP-NET. 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 SomaKit TOC with the following indication:

'After radiolabelling with gallium (^{68}Ga) chloride solution, the solution of gallium (^{68}Ga) edotreotide obtained is indicated for Positron Emission Tomography (PET) imaging of somatostatin receptor overexpression in adult patients with confirmed or suspected well-differentiated gastro-enteropancreatic neuroendocrine tumours (GEP-NET) for localizing primary tumours and their metastases'.

This falls within the scope of the product's designated orphan indication, which is: 'diagnosis of gastro-entero-pancreatic neuroendocrine tumours'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2015. GEP-NETs remain debilitating in the long term or life threatening,

[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 the same therapeutic indication cannot be placed on the market.

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particularly due to the potentially severe symptoms, and the poor outcome in patients whose tumours have spread locally or to other parts of the body.

Prevalence of the condition

The sponsor provided updated information on the prevalence of GEP-NETs 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 GEP-NETs 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 still estimated to be approximately 3.5 people in 10,000. This is equivalent to a total of around 180,000 people in the EU.

Existence of other methods of diagnosis

At the time of the review of the orphan designation, other methods were authorised in the EU for the diagnosis of GEP-NETs. Those available included other medicines labelled with the radioactive elements indium-(^{111}In), iodine-(^{123}I) or technetium-(^{99m}Tc).

Significant benefit of SomaKit TOC

The COMP concluded that the claim of a significant benefit of SomaKit TOC in the diagnosis of GEP-NETs is justified on the basis of improved accuracy in detecting GEP-NETs compared with other available products, which thereby improves how GEP-NET could be managed.

Therefore, although other methods for the diagnosis of this condition have been authorised in the EU, the COMP concluded that SomaKit TOC is of significant benefit to patients affected by GEP-NETs.

Conclusions

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