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EMA/COMP/639247/2016
Committee for Orphan Medicinal Products

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

Onivyde (irinotecan) for the treatment of pancreatic cancer

During its meeting of 6-8 September 2016, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/11/933 for Onivyde (irinotecan[1]), as an orphan medicinal product for the treatment of pancreatic cancer. 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 pancreatic cancer. 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 Onivyde for:

'treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), in adult patients who have progressed following gemcitabine based therapy'.

Metastatic adenocarcinoma of the pancreas is a form of pancreatic cancer. The CHMP indication therefore falls within the scope of the product's designated orphan indication, which is: 'pancreatic cancer'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2011. Pancreatic cancer remains a life-threatening condition that is associated with shortened life expectancy.

[1] Previously known as liposomal irinotecan
[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 of the condition

The sponsor provided updated information on the prevalence of pancreatic cancer based on data from the European Cancer Observatory (IARC), the Globocan 2012 database, and 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 pancreatic cancer 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 approximately 1.6 people in 10,000. This is equivalent to a total of around 82,000 people in the EU.

Existence of other methods of treatment

The COMP noted that, at the time of the review of the orphan designation, the main treatments for pancreatic cancer included the medicines mitomycin-c, 5-fluorouracil, gemcitabine, erlotinib and protein-bound nanoparticle paclitaxel. These medicines were given to patients who had not been treated before (first-line therapy).

Significant benefit of Onivyde

The COMP concluded that the claim of a significant benefit of Onivyde in pancreatic cancer is justified on the basis of the results of a clinical study in patients with metastatic adenocarcinoma of the pancreas who had been previously treated with gemcitabine-based therapy. No medicines are currently authorised for these patients. The study showed that Onivyde used together with 5-fluorouracil and leucovorin prolonged patients' lives.

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

Conclusions

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

Further information on the current regulatory status of Onivyde 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.