24 June 2015
EMA/COMP/236650/2015
Committee for Orphan Medicinal Products

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

Lenvima (lenvatinib) for the treatment of follicular and papillary thyroid cancers

During its meeting of 14 to 16 April 2015, the Committee for Orphan Medicinal Products (COMP) reviewed the designations EU/3/13/1119 and EU/3/13/1121 for Lenvima (lenvatinib) as an orphan medicinal product for the treatment of follicular and papillary thyroid cancers. 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 conditions, 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 follicular and papillary thyroid cancer. 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 Lenvima for:

'treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma, refractory to radioactive iodine'.

This falls within the scope of the product's designated orphan indications, which are: follicular and papillary thyroid cancers.

The COMP concluded that there had been no change in the seriousness of the conditions since the orphan designation in 2013. Follicular and papillary thyroid cancers remain conditions that are debilitating in the long term and life threatening, particularly when the cancer does not respond to treatment and spreads to other parts of the body.

[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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Prevalence of the condition

The sponsor provided updated information on the prevalence of follicular and papillary thyroid cancers based on data from the 2012 Globocan database.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of follicular and papillary thyroid cancers 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 of follicular thyroid cancer was estimated to be approximately 0.6 people in 10,000, and the prevalence for papillary thyroid cancer was approximately 2.4 people in 10,000. This is equivalent to a total of around 31,000 people in the EU with follicular thyroid cancer, and around 123,000 people in the EU with papillary thyroid cancer.

Existence of other methods of treatment

At the time of the review of the orphan designation, the main treatment for follicular and papillary thyroid cancers in the EU was surgery to remove the thyroid, followed by therapy using radioactive iodine (^{131}I) to destroy any remaining thyroid cells. In 2014, the medicine Nexavar (sorafenib) was authorised in the EU for the treatment of those patients whose differentiated (papillary/follicular/Hürthle cell) thyroid cancer had progressed or spread locally or to other parts of the body and did not respond to treatment with radioactive iodine.

Significant benefit of Lenvima

The COMP concluded that the claim of a significant benefit of Lenvima in follicular and papillary thyroid cancers is justified because Lenvima has been shown to improve progression-free survival (how long the patients lived without their disease getting worse) of patients whose cancer had progressed and had not responded to treatment with radioactive iodine. This is based on a main study in 392 patients, which showed that patients taking Lenvima lived an average of 18.3 months without their disease getting worse. This compares favorably with a progression-free survival of 10.8 months seen in patients treated with Nexavar in another study with a similar design to that with Lenvima.

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

Conclusions

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