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Press Office

Press release

Accelerated assessment fast-tracks Lenvima to benefit patients with thyroid cancer

Lenvima offers treatment option for patients who no longer respond to standard therapy

The European Medicines Agency (EMA) has recommended marketing authorisation for Lenvima (lenvatinib) for the treatment of adults with progressive, locally advanced or metastatic differentiated thyroid carcinoma (DTC), whose disease has progressed despite receiving radioactive iodine.

Lenvima was reviewed under EMA's accelerated assessment programme, as it provides a new treatment option for these patients.

Thyroid cancer is a rare disease which affects the thyroid, a small gland at the base of the neck that produces thyroid hormones. DTC is the most common type of thyroid cancer. It is generally treated with surgery, radioactive iodine and thyroxine therapy to suppress thyroid-stimulating hormone (TSH). Most people have a good prognosis following standard treatments. However, in a small group of patients, the cancer progresses despite treatment with radioactive iodine.

These patients currently have few treatment options. Patients may not experience symptoms of their disease until the cancer has progressed to an advanced stage and their prognosis is very poor.

Lenvima is a tyrosine kinase inhibitor. Tyrosine kinase inhibitors are a class of medicines that work by blocking certain enzymes known as tyrosine kinases. These enzymes can be found in some receptors on the surface of cancer cells and are involved in the growth and spread of cancer cells, and in the blood vessels that supply the tumours. To date, one tyrosine kinase inhibitor, Nexavar (sorafenib), has been approved in the European Union (EU) for the treatment of DTC in patients who no longer respond to treatment with radioactive iodine.

Because the type of cancer targeted by Lenvima is rare, the medicine received an orphan designation in 2013. Orphan designation and the associated incentives such as scientific advice are among the Agency's most important instruments to encourage the development of medicines for patients suffering from rare diseases.

The main study on which Lenvima's recommendation is based is a phase III trial including 392 patients with progressive DTC no longer responding to radioactive iodine, who were randomly assigned to

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receive either Lenvima or placebo. The study showed that patients treated with Lenvima lived on average 14.7 months longer without their disease progressing than patients treated with placebo.

A large proportion of people receiving Lenvima during the studies needed to reduce the dose or interrupt treatment because of side effects (mainly high blood pressure and excess protein in the urine). Overall EMA's Committee for Medicinal Products for Human Use (CHMP) considered that Lenvima has a safety profile which is consistent with other similar therapies and that side effects were predictable and manageable. However, the CHMP has requested a further study to investigate the most appropriate starting dose of Lenvima to optimise the benefits and reduce risks for patients who will be treated with the medicine.

The opinion adopted by the CHMP at its March 2015 meeting is an intermediary step on Lenvima's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on EU-wide marketing authorisation. Once a marketing authorisation has been granted, a decision about price and reimbursement will then take place at the level of each Member State considering the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Lenvima is Eisai Europe Ltd.
3. This medicine received an orphan designation from the Committee for Orphan Medicinal Products (COMP) in April 2013. Following the positive CHMP opinion, the COMP routinely assesses whether the orphan designation should be maintained.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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