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Press Office

Press release

Two new medicines for advanced kidney cancer

Cabometyx and Kisplyx provide additional treatment options for patients with unmet medical need

The European Medicines Agency (EMA) has recommended granting marketing authorisations in the European Union (EU) for two medicines for the treatment of advanced renal cell carcinoma (kidney cancer).

Cabometyx (cabozantinib) and Kisplyx (lenvatinib) are indicated for the treatment of adult patients with advanced renal cell carcinoma who have been previously treated with a vascular endothelial growth factor (VEGF)-inhibitor; Cabometyx is to be used as monotherapy while Kisplyx is for use in combination with everolimus.

Renal cell carcinoma is the most common form of kidney cancer in adults. Advanced renal cell carcinoma includes both metastatic disease and locally advanced renal cell carcinoma that cannot be removed by surgery. Despite the recent approval of new therapies for advanced renal cell carcinoma, many patients who do not respond to the existing treatments have a poor prognosis. Therefore new treatment options are needed.

Both Cabometyx and Kisplyx are tyrosine kinase inhibitors. This means that they 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.

Both active substances are already approved in the EU as different medicines for the treatment of thyroid cancer, an orphan condition. In December 2013, EMA recommended for approval another cabozantinib-containing medicine (Cometriq) to treat adults with medullary thyroid cancer. Another lenvatinib-containing medicine (Lenvima) was recommended for approval for the treatment of patients with thyroid carcinoma in March 2015.

For the treatment of renal cell carcinoma, both medicines were reviewed under EMA's accelerated assessment programme, as they target patients with an unmet medical need.

The main study on which Cabometyx's recommendation is based is a phase III trial involving 658 patients with metastatic renal cell carcinoma that had progressed after prior VEGF receptor tyrosine kinase inhibitor therapy. In this study, patients treated with Cabometyx had a longer period of time

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without their disease progressing (progression-free survival) compared to patients treated with everolimus (7.4 months compared to 3.8 months). In addition, preliminary results showed that patients treated with Cabometyx lived longer than patients treated with everolimus alone (median of 21.4 months compared to 16.5 months). The most frequent adverse reactions associated with cabozantinib include diarrhoea, fatigue, nausea, decreased appetite, palmar-plantar erythrodysaesthesia syndrome (hands and feet redness, swelling and pain), hypertension and vomiting. The Committee for Medicinal Products for Human Use (CHMP) concluded that the benefit/risk balance of Cabometyx is positive.

The main study on which Kisplyx's recommendation is based is a Phase Ib/II trial involving 153 patients with metastatic or unresectable renal cell carcinoma who received at least one prior VEGF targeted therapy and were treated either with the combination of Kisplyx with everolimus or with one of these agents. In this study, patients' progression-free survival was 12.8 months on average for patients treated with Kisplyx in combination with everolimus, compared to 5.6 months for patients treated with everolimus alone based on independent review of radiological images. In addition, encouraging signs of prolonged overall survival were seen in patients treated with the combination therapy. The most frequent adverse reactions include diarrhoea, fatigue, decreased appetite, vomiting, nausea and hypertension. Severe diarrhoea occurred at a higher frequency in the combination group than in the everolimus group.

The CHMP considered that the benefits of Kisplyx in combination with everolimus outweigh its risks but requested that post-authorisation studies be conducted to collect further data on the safety and efficacy of the combination therapy to complement data from the phase Ib/II trial.

The opinions adopted by the CHMP at its July 2016 meeting are an intermediary step on Cabometyx's and Kisplyx's and path to patient access. The CHMP opinions will now be sent to the European Commission for the adoption of decisions on EU-wide marketing authorisations. 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 the medicines 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 Cabometyx is Ipsen Pharma.
3. The applicant for Kisplyx is Eisai Europe Ltd.
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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