EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Zykadia recommended for approval in advanced non-small cell lung cancer

Medicine provides treatment option for patients with advanced ALK-positive non-small cell lung cancer previously treated with crizotinib

The European Medicines Agency (EMA) has recommended granting a conditional marketing authorisation for Zykadia (ceritinib). Zykadia is recommended for the treatment of adult patients with a type of lung cancer called anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC), when the disease is advanced and has already been treated with crizotinib.

Lung cancer is among the most common cancers in the world. Approximately 85% of all lung cancers are NSCLC. Most patients with NSCLC are found to have advanced disease at the time of diagnosis. Patients with locally advanced or metastatic NSCLC are generally treated with standard chemotherapy and/or radiation; however survival rates are poor. In a small proportion (2-7%) of people with NSCLC, the cancer cells contain defects in the gene responsible for a protein called anaplastic lymphoma kinase (ALK), which promotes the development of cancerous cells. People with this type of cancer are said to have 'ALK-positive' NSCLC.

Crizotinib is the only currently approved medicine for the treatment of previously treated locally advanced or metastatic ALK-positive NSCLC. However, even with treatment, disease progression typically occurs. Furthermore, not all patients respond to crizotinib treatment.

The Committee for Medicinal Products for Human Use (CHMP) considered that Zykadia provides a treatment option for a high unmet medical need in patients previously treated with crizotinib, as treatment options are currently very limited. Although the data supplied by the applicant show that Zykadia's benefits for treating patients with this condition were clinically relevant and outweighed the risks of adverse effects, the data available so far are based on two uncontrolled studies. The CHMP therefore recommended a conditional marketing authorisation and requested further results from ongoing studies and a comparative phase III study within the next three years.

The opinion adopted by the CHMP at its February 2015 meeting is an intermediary step on Zykadia'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

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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 Zykadia is Novartis Europharm Ltd.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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