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Zykadia (*ceritinib*)

An overview of Zykadia and why it is authorised in the EU

What is Zykadia and what is it used for?

Zykadia is a cancer medicine used on its own to treat adults with a type of lung cancer called non-small-cell lung cancer (NSCLC), when the disease is advanced. It is only used if the NSCLC is 'ALK-positive', which means that the cancer cells have certain defects affecting the gene responsible for a protein called ALK (anaplastic lymphoma kinase).

Zykadia contains the active substance ceritinib.

How is Zykadia used?

Zykadia can only be obtained with a prescription and treatment must be started and supervised by a doctor who is experienced in using cancer medicines. The presence of genetic defects affecting ALK ('ALK-positive' status) has to be confirmed in advance by appropriate methods.

The medicine is available as capsules (150 mg). The recommended dose is 450 mg (3 capsules) once a day taken with food at the same time each day. The doctor may decide to reduce the dose or stop treatment temporarily if side effects occur. In certain cases treatment should be permanently stopped.

For more information about using Zykadia, see the package leaflet or contact a doctor or pharmacist.

How does Zykadia work?

ALK belongs to a family of proteins called receptor tyrosine kinases, which are involved in the growth of cells and the development of new blood vessels that supply them. In patients with ALK-positive NSCLC, an abnormal form of ALK is produced that stimulates the cancer cells to divide and grow in an uncontrolled fashion. The active substance in Zykadia, ceritinib, works by blocking the activity of ALK, thereby reducing the growth and spread of the cancer.

What benefits of Zykadia have been shown in studies?

Zykadia has been shown to be effective at treating advanced, ALK-positive NSCLC in three main studies in patients whose disease progressed despite previous treatment with the medicine crizotinib:

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In two of these studies, involving 303 patients, the medicine was not compared with any other treatment. Response to treatment was assessed using body scans and standardised criteria used for solid tumours, with complete response being when the patient had no remaining signs of the cancer. In one study 56% of patients given Zykadia (92 of 163) were considered by the treating doctors to have shown a complete or partial response to the medicine. The average length of response was 8.3 months. In the second study, the overall response rate was 41% (57 of 140 patients) and the average length of response was 10.6 months.

In the third study in 231 patients, Zykadia was compared with standard chemotherapy (medicines to treat cancer). Results showed that patients given Zykadia lived for an average of 5.4 months without their disease getting worse (progression-free survival) compared with 1.6 months in patients given standard chemotherapy.

Zykadia has also been shown to be effective at treating patients who had not been treated before in a study in 376 patients. Patients given Zykadia lived for an average of 16.6 months without their disease getting worse compared with 8.1 months in patients given standard chemotherapy.

What are the risks associated with Zykadia?

The most common side effects with Zykadia (which may affect 1 or more people in 10) are diarrhoea, nausea (feeling sick), vomiting, tiredness, abnormal liver tests, abdominal (belly) pain, decreased appetite, weight loss, constipation, rash, increases in the level of a waste product called creatinine in the blood (a possible sign of kidney problems), oesophageal disorder (problems affecting the food pipe) and anaemia (low levels of red blood cells). The most common severe reactions (which may affect 1 or more people in 20) are abnormal liver tests, tiredness, diarrhoea, nausea, vomiting and hyperglycaemia (high blood sugar).

For the full list of side effects and restrictions with Zykadia, see the package leaflet.

Why is Zykadia authorised in the EU?

Zykadia has been shown to be effective at treating patients whose disease progressed during or shortly after treatment with crizotinib and who currently have very limited treatment options, as well as patients who have not been treated before. Regarding safety, the adverse effects with Zykadia generally appeared manageable.

The European Medicines Agency therefore decided that Zykadia's benefits are greater than its risks and recommended that it be approved for use in the EU.

Zykadia was originally given 'conditional approval' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

What measures are being taken to ensure the safe and effective use of Zykadia?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zykadia have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zykadia are continuously monitored. Side effects reported with Zykadia are carefully evaluated and any necessary action taken to protect patients.

Other information about Zykadia

Zykadia received a conditional marketing authorisation valid throughout the EU on 06 May 2015. This was switched to full marketing authorisation on 26 July 2017.

Further information on Zykadia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 04-2018.