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Lytgobi (*futibatinib*)

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

What is Lytgobi and what is it used for?

Lytgobi is a cancer medicine used to treat adults with cholangiocarcinoma (biliary tract cancer or cancer of the bile ducts) when the cancer cells have an abnormal form of a receptor (target) called FGFR2 on their surface. Lytgobi is used when the cancer has spread to other parts of the body or cannot be removed by surgery and has worsened after previous treatment with at least one cancer medicine.

Lytgobi contains the active substance futibatinib.

How is Lytgobi used?

Lytgobi can only be obtained with a prescription and treatment must be started by a doctor experienced in the diagnosis and treatment of the disease. The medicine is available as tablets, to be taken by mouth once a day. Treatment can continue for as long as the patient benefits from it and side effects are manageable.

For more information about using Lytgobi, see the package leaflet or contact your doctor or pharmacist.

How does Lytgobi work?

This medicine is a tyrosine kinase inhibitor, meaning that it blocks the activity of enzymes known as tyrosine kinases. The active substance in Lytgobi, futibatinib, blocks receptors (targets) called fibroblast growth factor receptors (FGFRs), which are found on the surface of cells and help regulate cell growth. Cancer cells with changes in the FGFR gene have an abnormal form of this protein which makes them grow uncontrollably. By blocking FGFRs, futibatinib can prevent the growth of such cancer cells.

What benefits of Lytgobi have been shown in studies?

Lytgobi was investigated in a main study involving 103 adults with cholangiocarcinoma that had spread or that could not be removed with surgery, and who had previously received at least one systemic

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treatment. All patients had alterations (changes) in the FGFR2 gene. All patients in the study were given Lytgobi.

When patients were given Lytgobi, the tumour size decreased in 42% (43 out of 103) of them and the response was maintained for almost 10 months on average.

What are the risks associated with Lytgobi?

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

The most common side effects with Lytgobi (which may affect more than 1 in 5 people) include hyperphosphataemia (high levels of phosphates in the blood), nail disorders (such as nails separating from the nail bed, poor formation of the nail or change in colour of the nails), constipation, hair loss, diarrhoea, dry mouth, tiredness, nausea (feeling sick), dry skin, increased levels of liver enzymes in the blood, abdominal (belly) pain, stomatitis (inflammation of the lining of the mouth), vomiting, hand-foot syndrome (a reaction to therapy causing redness, swelling, peeling or tenderness, mainly on the hands or feet), arthralgia (joint pain), and decreased appetite.

The most common serious side effects with Lytgobi (which may affect more than 1 in 100 people), include intestinal obstruction and migraine.

Why is Lytgobi authorised in the EU?

At the time of approval, treatment options were limited for patients with locally advanced or metastatic cholangiocarcinoma who had previously received systemic therapy and who had FGFR2 alterations. Treatment with Lytgobi resulted in a durable response in about 40% of these patients that was maintained for almost 10 months on average, with side effects that could be managed with other medicines or dose adjustments. The medicine has been given 'conditional authorisation'. This means that the European Medicines Agency decided that the benefits of Lytgobi are greater than its risks, but the company will have to provide additional evidence after authorisation.

Conditional authorisation is granted on the basis of less comprehensive data than are normally required. It is granted for medicines that fulfil an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the medicines while waiting for further evidence. Every year, the European Medicines Agency will review any new information that becomes available until data become comprehensive and this overview will be updated as necessary.

Since Lytgobi was given conditional authorisation, at the time of authorisation the company marketing Lytgobi was required to provide data from an ongoing study on the effectiveness and safety of the medicine.

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

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

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

Other information about Lytgobi

Lytgobi received a conditional marketing authorisation valid throughout the EU on 4 July 2023.

Further information on Lytgobi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Lytgobi

This overview was last updated in 07-2023.