26 April 2023
EMA/CHMP/169349/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lytgobi

futibatinib

On 26 April 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Lytgobi[3], intended for the second-line treatment of locally advanced or metastatic cholangiocarcinoma characterized by fusion or rearrangements of fibroblast growth factor receptor (FGFR) 2.

The applicant for this medicinal product is Taiho Pharma Netherlands B.V.

Lytgobi will be available as a 4 mg film-coated tablet. The active substance of Lytgobi is futibatinib, a protein kinase inhibitor (ATC code: L01EN04), which is an irreversible kinase inhibitor of FGFR 1, 2, 3 and 4.

The benefit of Lytgobi is its ability to increase the partial response rate after first-line treatment, which is maintained for a median of 10 months.

The most common side effects are hyperphosphataemia, nail disorders, constipation, alopecia, diarrhoea, dry mouth, fatigue, nausea, dry skin, increased aspartate aminotransferase, abdominal pain, stomatitis, vomiting, palmar-plantar erythrodysaesthesia syndrome, arthralgia and decreased appetite.

The full indication is:

> Lytgobi monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Lytgobi should be prescribed by physicians experienced in the in the diagnosis and treatment of patients with biliary tract cancer.

Detailed recommendations for the use of this product will be described in the summary of product

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.