LYTGOBI® (futibatinib) tablets 4 mg

VETERANS ADMINISTRATION AND TRICARE STATUS

VA: Approved, Non-Formulary, Prescriptions Permitted With Criteria for Use

TRICARE: Approved on the TRICARE Uniform Formulary With Prior Authorization Required

LYTGOBI is a targeted treatment for advanced intrahepatic cholangiocarcinoma

42% **overall response rate**[a] was observed in patients with previously treated, locally advanced or metastatic iCCA[b]

CONTINUOUS, ONCE-DAILY ORAL DOSING

The recommended starting dose of LYTGOBI is 20 mg (five 4-mg tablets) taken orally once daily until disease progression or unacceptable toxicity occurs.

iCCA, intrahepatic cholangiocarcinoma; VA, Veterans Affairs.

[a]Responses were partial.

[b]This was a multicenter, open-label, single-arm trial, evaluating the efficacy of LTYGOBI in 103 patients with previously treated, unresectable, locally advanced or metastatic iCCA. Patients received LYTGOBI 20 mg orally once daily until disease progression or unacceptable toxicity. A major efficacy outcome measure was overall response rate (ORR). The ORR was 42% (CI 95%: 32, 52), all partial responses.

INDICATION AND USAGE

LYTGOBI is indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Ocular Toxicity:** LYTGOBI can cause Retinal Pigment Epithelial Detachment (RPED), which may cause symptoms such as blurred vision. RPED occurred in 9% of 318 patients who received LYTGOBI across clinical trials. The median time to first onset

Please see additional Important Safety Information on other side and full Prescribing Information at LYTGOBI.com/PI.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Ocular Toxicity (cont'd):** of RPED was 40 days. RPED led to dose interruption of LYTGOBI in 1.3% of patients, dose reduction in 1.6% of patients, and permanent discontinuation in 0.3% of patients. Perform a comprehensive ophthalmological examination, including optical coherence tomography (OCT) of the macula, prior to initiation of therapy, every 2 months for the first 6 months, and every 3 months thereafter. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of LYTGOBI. Withhold or reduce the dose of LYTGOBI as recommended. Dry Eye/Corneal Keratitis: Among 318 patients who received LYTGOBI across clinical trials, dry eye occurred in 15% of patients. Treat patients with ocular demulcents as needed.
- **Hyperphosphatemia and Soft Tissue Mineralization:** LYTGOBI can cause hyperphosphatemia leading to soft tissue mineralization, calcinosis, nonuremic calciphylaxis, and vascular calcification. Hyperphosphatemia was reported in 88% of 318 patients treated with LYTGOBI across clinical trials with a median time of onset of 5 days (range 3-117). Phosphate binders were received by 77% of patients who received LYTGOBI. Monitor for hyperphosphatemia throughout treatment. Initiate a low-phosphate diet and phosphate-lowering therapy when serum phosphate level is ≥5.5 mg/dL; initiate or intensify phosphate-lowering therapy when >7 mg/dL; reduce dose, withhold, or permanently discontinue LYTGOBI based on duration and severity of hyperphosphatemia.
- **Embryo-fetal Toxicity:** Based on findings in an animal study and its mechanism of action, LYTGOBI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential, and males with female partners of reproductive potential, to use effective contraception during treatment with LYTGOBI and for 1 week after the last dose.

ADVERSE REACTIONS

- **Serious adverse reactions** occurred in 39% of patients receiving LYTGOBI, and in ≥2% of patients included pyrexia (3.9%), gastrointestinal hemorrhage (3.9%), ascites (2.9%), musculoskeletal pain (2.9%), and bile duct obstruction (2.9%).
- **The most common adverse reactions** (≥20%) were nail toxicity (47%), musculoskeletal pain (43%), constipation (39%), diarrhea (39%), fatigue (37%), dry mouth (35%), alopecia (34%), stomatitis (30%), abdominal pain (30%), dry skin (29%), arthralgia (25%), dysgeusia (25%), dry eye (25%), nausea (24%), decreased appetite (23%), urinary tract infection (23%), palmar-plantar erythrodysesthesia syndrome (21%), and vomiting (20%).
- **The most common laboratory abnormalities** (≥20%) were increased phosphate(97%), increased creatinine (58%), decreased hemoglobin (52%), increased glucose (52%), increased calcium (51%), decreased sodium (51%), decreased phosphate (50%), increased alanine aminotransferase (50%), increased alkaline phosphatase (47%), decreased lymphocytes (46%), increased aspartate aminotransferase (46%), decreased platelets (42%), increased activated partial thromboplastin time (36%), decreased leukocytes (33%), decreased albumin (31%), decreased neutrophils (31%), increased creatine kinase (31%), increased bilirubin (28%), decreased glucose (25%), increased prothrombin international normalized ratio (25%), and decreased potassium (22%).

DRUG INTERACTIONS

- **Dual P-gp and Strong CYP3A Inhibitors:** Avoid concomitant use of drugs that are dual P-gp and strong CYP3A inhibitors.
- **Dual P-gp and Strong CYP3A Inducers:** Avoid concomitant use of drugs that are dual P-gp and strong CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Because of the potential for serious adverse reactions from LYTGOBI in breastfed children, advise women not to breastfeed during treatment and for 1 week after the last dose.
- **Hepatic Impairment:** Patients with hepatic impairment may have the potential for increased adverse reactions compared to patients with normal hepatic function.

Please see full Prescribing Information at LYTGOBI.com/PI for complete details.

Reference: LYTGOBI. Prescribing Information. Taiho Oncology, Inc; 2024.

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