## A GUIDE FOR NURSES

This guide is a resource to assist you with the conversations you have with your patients about using LYTGOBI® (futibatinib) tablets.

LYTGOBI®
(futibatinib) tablets 4 mg

LYTGOBI can provide

# The power you want. The care patients need.

- **42%** ORR* (95% CI: 32%, 52%)[1]
- **9.7 months** mDoR (95% CI: 7.6, 17.1) (N=103)[1]

Take on advanced cholangiocarcinoma (CCA) with LYTGOBI, an approved irreversibly binding *FGFR* inhibitor designed to help you target appropriate patients and offer personalized support along their treatment journey.[1-3]

## 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).

## SELECTED 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.

*Responses were partial in the single-arm, phase 2 FOENIX-CCA2 study (TAS-120-101).[1]

**Please see Important Safety Information throughout and full Prescribing Information in pocket or at LYTGOBI.com/PI.**

CI=confidence interval; *FGFR*=fibroblast growth factor receptor; mDoR=median duration of response; ORR=overall response rate.

# Efficacy and safety assessed in a phase 2 study[1,4,5]

FOENIX-CCA2 (TAS-120-101) was a multicenter, open-label, single-arm, phase 2 study in patients with unresectable locally advanced or metastatic intrahepatic CCA harboring an *FGFR2* fusion or rearrangement.

## PATIENTS

**Key eligibility criteria**

- Unresectable or metastatic intrahepatic CCA
- *FGFR2* fusions or other rearrangements
- Measurable disease per RECIST v1.1
- Prior gemcitabine + platinum-based chemotherapy
- Progression after ≥1 systemic therapy
- ECOG PS 0 or 1
- No prior treatment with *FGFR* inhibitor

## PATIENT BASELINE CHARACTERISTICS (N=103)

- Median age was 58 years, with a range of 22-79 years
- ECOG PS was Category 0 in 47% of patients and Category 1 in 53%
- 100% of patients had at least 1 prior treatment; 30% had at least 2; and 23% had ≥3
- 78% of patients had fusions, and 22% had rearrangements, as their *FGFR2* aberration*
- 22% of patients ≥65 years
- 56% of patients were female
- Races were: 50% White, 29% Asian, 8% Black or African American, 1% Native Hawaiian or Other Pacific Islander, 13% unknown

## TREATMENT

**LYTGOBI® (futibatinib) tablets** 20 mg orally once daily, continuously

Treatment was administered until disease progression, drug intolerance, withdrawal of consent, or death.

A maximum of 2 dose reductions (to 16 mg and then to 12 mg) were permitted to manage treatment-emergent ARs.†

Note: Prophylactic treatment was not administered for hyperphosphatemia.[5]

## ENDPOINTS

**Primary (by IRC):**

- Overall response rate

**Secondary:**

- Duration of response
- DCR
- PFS
- OS
- Safety
- Patient-reported outcomes

## FOLLOW-UP

Follow-up continued for up to 18 months after enrollment of last patient.

AR=adverse reaction; DCR=disease control rate; ECOG PS=Eastern Cooperative Oncology Group performance status; IRC=independent review committee; OS=overall survival; PFS=progression-free survival; RECIST v1.1=Response Evaluation Criteria for Solid Tumors version 1.1.

*Determined by Foundation Medicine Central (n=68), Foundation Medicine Local reports (n=25), or by local testing (n=10); 2 patients had *FGFR2* mutations in addition to fusions.[6]

†Treatment was discontinued if treatment-emergent ARs did not resolve after 2 dose modifications or if the next cycle of treatment was delayed >21 days.[4]

## SELECTED IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (continued)

- **Ocular Toxicity (continued):** The median time to first onset 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.

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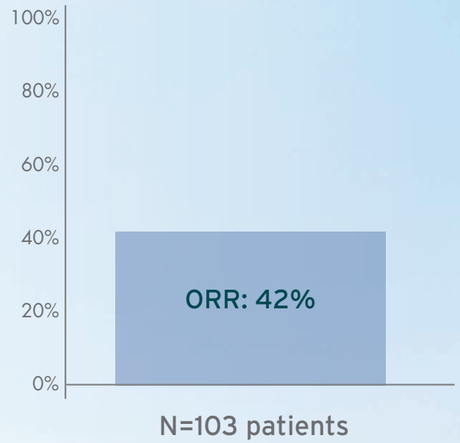
## Powered to enable a response[1]

**42% of patients responded to treatment with LYTGOBI® (futibatinib) tablets**

**Primary endpoint: overall response rate (ORR)**




The **ORR** for LYTGOBI was

**42%**

(95% CI: 32%, 52%)

- PR: 42%

**2.5 months median TTR** (range: 0.7-7.4)

PR=partial response; TTR=time to response.

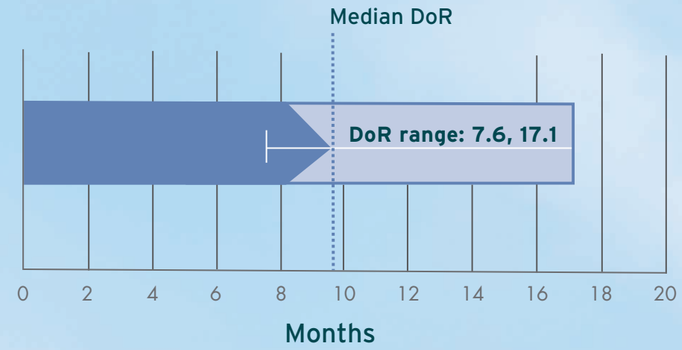
## Durable cholangiocarcinoma treatment results[1]

**Secondary endpoint: duration of response (DoR)**

Median DoR

**9.7 Months**

(95% CI: 7.6, 17.1)




**72%** of responders (n=31) had responses that lasted ≥6 months

**14%** of responders (n=6) had responses that lasted ≥1 year

### SELECTED IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (continued)

- **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 final dose.

### ADVERSE REACTIONS

- **Serious adverse reactions** occurred in 39% of patients receiving LYTGOBI, and in ≥2% of patients included pyrexia, gastrointestinal hemorrhage, ascites, musculoskeletal pain, and bile duct obstruction.
- **The most common adverse reactions** (≥20%) were nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, and vomiting.

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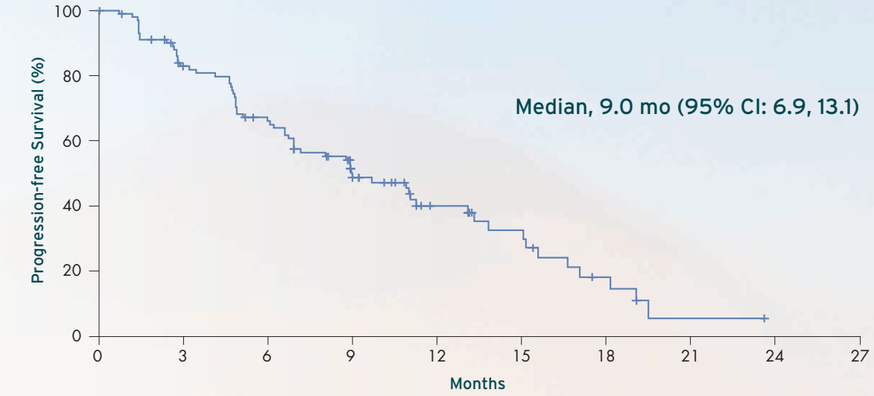
# FOENIX-CCA2: Additional Endpoints[1,5,6]

## LYTGOBI® (futibatinib) tablets received accelerated approval from the FDA based on overall response rate and duration of response in a single-arm study[1]

- For this reason, a confirmatory phase 3 study in cholangiocarcinoma is underway[1]
- Progression-free survival, overall survival, and disease control rate were secondary endpoints that were studied in FOENIX-CCA2 and that are not reflected in the full Prescribing Information
- Due to potential variability in the natural history of the disease, a single-arm study may not adequately characterize these time-to-event endpoints and the results may not be interpretable
- **This data presentation is neither intended to draw conclusions regarding the efficacy of LYTGOBI nor to imply that there is a treatment effect of LYTGOBI on these time-to-event endpoints and the results should be interpreted with caution**

### Progression-free Survival (PFS)[5]

**Kaplan-Meier estimate of PFS (N=103)**




- Median follow-up at time of data cutoff was 17.1 months

**SELECTED IMPORTANT SAFETY INFORMATION**

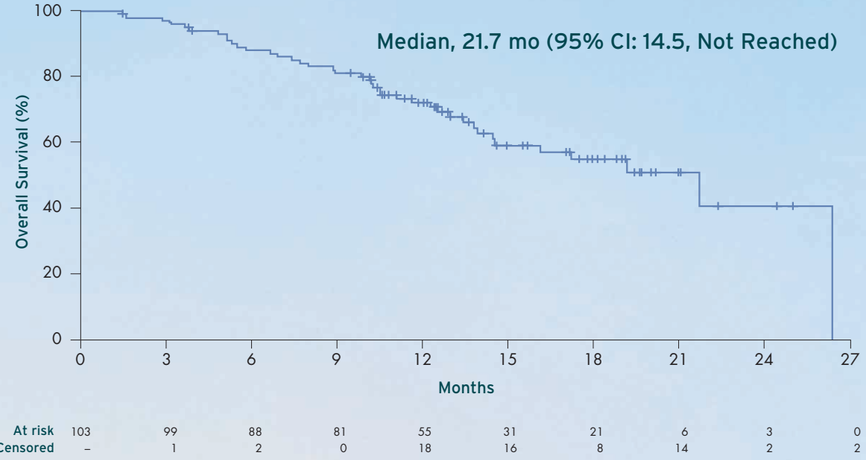
**ADVERSE REACTIONS (continued)**

- **The most common laboratory abnormalities** (≥20%) were increased phosphate, increased creatinine, decreased hemoglobin, increased glucose, increased calcium, decreased sodium, decreased phosphate, increased alanine aminotransferase, increased alkaline phosphatase, decreased lymphocytes, increased aspartate aminotransferase, decreased platelets, increased activated partial thromboplastin time, decreased leukocytes, decreased albumin, decreased neutrophils, increased creatine kinase, increased bilirubin, decreased glucose, increased prothrombin international normalized ratio, and decreased potassium.



### Overall Survival (OS)[5,6]

**Kaplan-Meier estimate of OS (N=103)**




- At the time of data cutoff: Median follow-up was 17.1 months; the OS data were not mature; 40 patients died. All patients had discontinued therapy prior to their death with the predominant reason for discontinuation being progression of disease in 89% of patients.[5,6]

### Disease Control Rate (DCR)[5,6]

- Disease control rate was 83% (n=85; 95% CI: 74, 89)[8]
- FOENIX-CCA2 was a single-arm study[6]
  - In this setting, the DCR results may reflect the natural history of cholangiocarcinoma in an individual patient, rather than the direct effect of treatment

### Results Observed in Patient Subgroup[5]

- Additionally, this subgroup analysis was considered exploratory (ie, hypothesis-generating) and did not control for Type 1 error (false positive rate); therefore, it is not possible to ascertain the probability that these findings were attributable to treatment with LYTGOBI

### Supplementary Results[5,7]

**Efficacy results at extended follow-up**

At a nonprespecified follow-up analysis conducted 8 months after the primary analysis (data cutoff, May 29, 2021; median follow-up, 25.0 months), efficacy in the overall study population was maintained with an ORR of 41.7%, a DCR of 82.5%, a median DoR of 9.5 months, a median PFS of 8.9 months, and a median OS of 20.0 months. The extended follow-up data were collected after the primary analysis and are descriptive in nature and results should be interpreted with caution.

DCR is the sum of complete response, partial response, and stable disease.

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# An established safety profile with LYTGOBI[1]

## ARs (≥15%) in patients receiving LYTGOBI® (futibatinib) tablets in Study TAS-120-101

| LYTGOBI (N=103) | | |
|---|---|---|
| **ARs** | **All grades[a] (%)** | **Grade 3 (%)** |
| **Skin and subcutaneous tissue disorders** | | |
| Nail toxicity[b] | 47.0 | 1.9 |
| Alopecia | 34.0 | 0 |
| Dry skin | 29.0 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 21.0 | 4.9 |
| **Gastrointestinal disorders** | | |
| Constipation | 39.0 | 0 |
| Diarrhea[c] | 39.0 | 1.0 |
| Dry mouth | 35.0 | 0 |
| Stomatitis[d] | 30.0 | 6.0 |
| Abdominal pain[e] | 30.0 | 2.9 |
| Nausea | 24.0 | 1.9 |
| Vomiting[f] | 20.0 | 1.0 |

| LYTGOBI (N=103) | | |
|---|---|---|
| **ARs** | **All grades[a] (%)** | **Grade 3 (%)** |
| **General disorders** | | |
| Fatigue[g] | 37.0 | 8.0 |
| **Metabolism and nutrition disorders** | | |
| Decreased appetite | 23.0 | 2.9 |
| **Musculoskeletal and connective tissue disorder** | | |
| Musculoskeletal pain[h] | 43.0 | 3.9 |
| Arthralgia[i] | 25.0 | 0 |
| **Eye disorders** | | |
| Dry eye[j] | 25.0 | 1.0 |
| **Nervous system disorders** | | |
| Dysgeusia[k] | 25.0 | 0 |
| **Infections and infestations** | | |
| Urinary tract infection[l] | 23.0 | 2.9 |
| **Investigations** | | |
| Weight decreased | 18.0 | 3.9 |

[a] Graded per NCI CTCAE 4.03.[1]
[b] Includes nail toxicity, nail disorder, nail discoloration, nail dystrophy, nail hypertrophy, nail infection, nail pigmentation, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomycosis, and paronychia.[1]
[c] Includes diarrhea, colitis, and gastroenteritis.[1]
[d] Includes stomatitis, glossitis, mouth ulceration, mucosal inflammation, pharyngeal inflammation, and tongue ulceration.[1]
[e] Includes abdominal pain, abdominal discomfort, abdominal pain upper, gastrointestinal pain, and hepatic pain.[1]
[f] Includes vomiting and hematemesis.[1]
[g] Includes fatigue and asthenia.[1]
[h] Includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal discomfort, musculoskeletal pain, musculoskeletal stiffness, myalgia, neck pain, non-cardiac chest pain, pain in extremity, and spinal pain.[1]
[i] Includes arthralgia and arthritis.[1]
[j] Includes dry eye, keratitis, lacrimation increased, photokeratitis, punctate keratitis, and ulcerative keratitis.[1]
[k] Includes dysgeusia, ageusia, and taste disorder.[1]
[l] Includes urinary tract infection, cystitis, and dysuria.[1]

- Among the most common (≥15%) ARs experienced by patients taking LYTGOBI in FOENIX-CCA2, no Grade 4 or 5 reactions occurred
- Clinically relevant adverse reactions occurring in ≤15% of patients included retinal pigment epithelial detachment (RPED, 7.8%)

**Use of LYTGOBI is also associated with the following serious risks: ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity.**

**Please see Important Safety Information throughout and full Prescribing Information in pocket or at LYTGOBI.com/PI.**



## Select laboratory abnormalities (≥10%) worsening from baseline in patients receiving LYTGOBI Study TAS-120-101

| LYTGOBI (N=103) | | |
|---|---|---|
| **Laboratory Abnormality[a]** | **All grades[b] (%)** | **Grades 3 or 4 (%)** |
| **Hematology** | | |
| Decreased hemoglobin | 52.0 | 6.0 |
| Decreased lymphocytes | 46.0 | 10.0 |
| Decreased platelets | 42.0 | 1.0 |
| Decreased leukocytes | 33.0 | 1.1 |
| Decreased neutrophils | 31.0 | 1.6 |
| **Chemistry** | | |
| Increased phosphate[c] | 97.0 | 39.0 |
| Increased creatinine[d] | 58.0 | 0.0 |
| Increased glucose | 52.0 | 4.9 |
| Increased calcium | 51.0 | 1.2 |
| Decreased sodium | 51.0 | 15.0 |
| Decreased phosphate | 50.0 | 20.0 |
| Increased alanine aminotransferase | 50.0 | 7.0 |
| Increased alkaline phosphatase | 47.0 | 4.9 |
| Increased aspartate aminotransferase | 46.0 | 13.0 |
| Decreased albumin | 31.0 | 2.4 |
| Increased creatine kinase | 31.0 | 5.0 |
| Increased bilirubin | 28.0 | 0.0 |
| Decreased glucose | 25.0 | 0.0 |
| Decreased potassium | 22.0 | 2.1 |
| Increased potassium | 16.0 | 2.0 |
| **Coagulation** | | |
| Increased activated partial thromboplastin time | 36.0 | 8.0 |
| Increased prothrombin international normalized ratio | 25.0 | 0.0 |

[a]Graded per NCI CTCAE 4.03.
[b]Percentages are based on patients with data at both baseline and at least one post-baseline data value.
[c]NCI CTCAE 4.03 does not define grades for increased phosphate. Laboratory value shift table categories were used to assess increased phosphorus levels (Grades ≥3 defined as >7 mg/dL).
[d]Graded based on comparison to upper limit of normal.

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# Managing common adverse reactions

## Tips for advising patients on how to help manage common adverse reactions

The following information may help your patients manage some of the common side effects they may experience while taking LYTGOBI® (futibatinib) tablets.

### Hyperphosphatemia[1]

- Patients should immediately inform you of any symptoms related to acute change in phosphate levels such as muscle cramps, numbness, or tingling around the mouth
- Advise your patients that the best way to limit phosphorus in the diet is to limit foods highest in phosphorus, including beverages that contain phosphorus (look for the letters "phos" in the ingredient list)

### Dry mouth[8]

- Patients can sip water throughout the day or suck on ice chips
- Sugar-free candy or sugar-free gum also minimizes the effects of dry mouth
- Consider prescribing saliva substitutes if your patient's mouth continues to be dry

### Diarrhea[8]

- Patients should try eating smaller meals throughout the day instead of 3 large meals
- Drinking at least 8 cups of water or other fluids each day is recommended
- Foods that are low in fiber and high in sodium or potassium are preferred
- Advise patients to contact their healthcare providers if diarrhea lasts more than 24 hours, or if they experience pain or cramping

### Constipation[8]

- Drinking at least 8 cups of water or other fluids each day is advised
- Staying active every day by walking or doing light exercise minimizes constipation
- Patients should eat foods that are high in fiber, such as whole-grain breads and cereals
- If your patient does not have a bowel movement for 2 days, the next step might be to suggest a fiber supplement, laxative, stool softener, or enema. Patients should not use these treatments without your approval.

### Tiredness[8]

- Patients could try relaxing activities like meditation or yoga
- Encourage them to eat well and try to drink at least 8 cups of water or other fluids each day
- They should plan time to rest during the day
- Getting at least 8 hours of sleep at night is suggested
- Your patients can try low-effort exercises like short walks to stay active

**SELECTED IMPORTANT SAFETY INFORMATION**

**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.

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# Managing common adverse reactions (continued)

## Hair loss[8]

- Advise them to be gentle when they wash their hair and to use mild shampoo and pat dry
- They should avoid items that can hurt one's scalp, such as heat-powered styling tools, hairspray or hair dye, or hair bands and clips
- Patients need to protect their scalp during and after hair loss by wearing a hat, turban, or scarf while outside, and to avoid extreme temperatures
- Patients could use a satin pillowcase to avoid friction while sleeping

## Dry skin[8]

- Advise patients to take quick showers or sponge baths instead of long, hot baths
- They should pat themselves dry after bathing
- Washing with a mild, moisturizing soap should help ease the effects of dry skin
- Patients should put on cream or lotion while their skin is still damp after washing
- Avoiding toiletries that contain alcohol is advised

**Prior to initiation of therapy, patients are required to undergo a comprehensive ophthalmological examination including optical coherence tomography, every 2 months for the first 6 months, and every 3 months thereafter and urgently at any time for visual symptoms.**

# Straightforward, continuous, once-daily oral dosing[1]

LYTGOBI® (futibatinib) tablets are 4 mg each. The recommended starting dose of LYTGOBI is 20 mg (5 tablets). LYTGOBI is taken orally once per day. It is taken continuously until disease progression or unacceptable toxicity occurs.

LYTGOBI can be taken with or without food. Patients should take their prescribed dose at the same time each day.

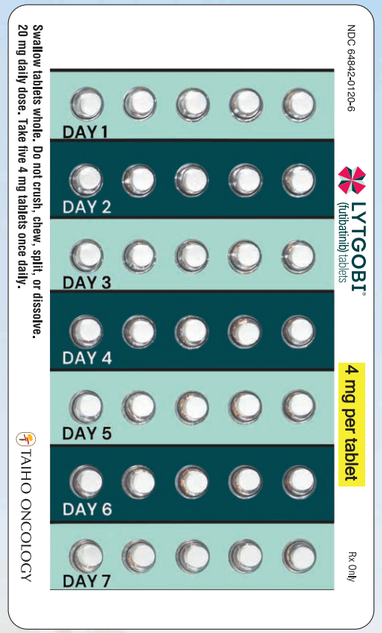
- Instruct patients to not crush, chew, split, or dissolve tablets
- Advise patients to inform their healthcare providers of all concomitant medications, including herbal and dietary supplements. Advise patients to avoid grapefruit products during treatment with LYTGOBI
- Instruct patients if they miss a dose by 12 or more hours or if they vomit after taking a dose, to resume dosing with the next scheduled dose. Extra tablets should not be taken to make up for the missed dose


*Tablet shown is actual size.*

Remember: Day 1 is row 1. Each row of tablets equals one daily dose.

## Starting dose

20 mg (five 4-mg tablets) once daily.




## SELECTED IMPORTANT SAFETY INFORMATION

### 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.

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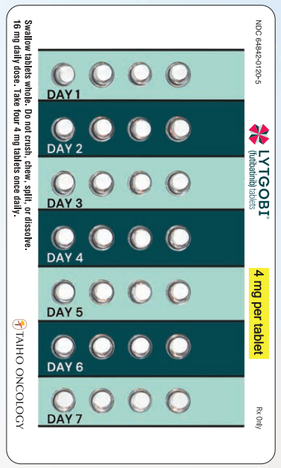
# Alternative DosePaks available[1]

**In the event that dose modifications are required, alternative DosePaks are available to make dosing convenient for patients.**

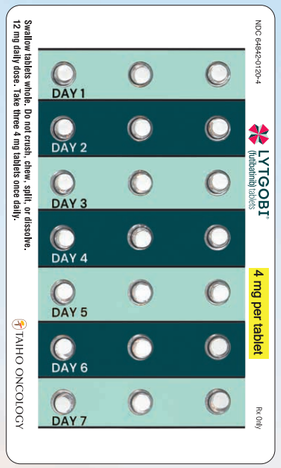
### First dose reduction[1]*

16 mg (four 4-mg tablets) once daily.




### Second dose reduction[1]*

12 mg (three 4-mg tablets) once daily.




*Permanently discontinue LYTGOBI if unable to tolerate 12 mg orally once daily.[1]

### How to store LYTGOBI

This package is child-resistant. Store LYTGOBI at room temperature between 68°F to 77°F (20°C to 25°C).

Keep LYTGOBI and all medicines out of the reach of children.

**SELECTED 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 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.

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# Recommended dosage modifications for adverse reactions[1]

**HYPERPHOSPHATEMIA**

| Severity | LYTGOBI® (futibatinib) tablets dose modifications |
|---|---|
| Serum phosphate ≥5.5 - ≤7.0 mg/dL | Continue LYTGOBI at the current dose and initiate phosphate-lowering therapy. Monitor serum phosphate weekly. |
| Serum phosphate >7.0 - ≤10.0 mg/dL | • Initiate or adjust phosphate-lowering therapy. Monitor serum phosphate weekly and<br>• Reduce LYTGOBI to next lower dose<br>– If the serum phosphate resolves to ≤7.0 mg/dL within 2 weeks after dose reduction, continue at this reduced dose<br>– If serum phosphate is not ≤7.0 mg/dL within 2 weeks, further reduce LYTGOBI to the next lower dose<br>– If serum phosphate is not ≤7.0 mg/dL within 2 weeks after the second dose reduction, withhold LYTGOBI until serum phosphate is ≤7.0 mg/dL and resume at the dose prior to suspending |
| Serum phosphate >10.0 mg/dL | • Initiate/intensify phosphate-lowering therapy and monitor serum phosphate weekly and<br>• Withhold LYTGOBI until phosphate is ≤7.0 mg/dL and resume LYTGOBI at the next lower dose<br>– Permanently discontinue LYTGOBI if serum phosphate is not ≤7.0 mg/dL within 2 weeks following 2 dose interruptions and reductions |

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# Recommended dosage modifications for adverse reactions (continued)[1]

## RETINAL PIGMENT EPITHELIAL DETACHMENT (RPED)

### LYTGOBI® (futibatinib) tablets dose modifications

Continue LYTGOBI at the current dose and continue periodic ophthalmic evaluation:
- If resolving within 14 days, continue LYTGOBI at the current dose
- If not resolving within 14 days, withhold LYTGOBI until resolving; then resume LYTGOBI at previous or a lower dose

## OTHER ADVERSE REACTIONS

### LYTGOBI dose modifications

- In the case of Grade 3* adverse reaction, withhold LYTGOBI until toxicity resolves to Grade 1 or baseline, then resume LYTGOBI
  - For hematological toxicities resolving within 1 week, at the dose prior to suspending
  - For other adverse reactions, at the next lower dose
- In the case of Grade 4* adverse reaction, permanently discontinue LYTGOBI

*Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE version 4.03).

**A brochure is available to help your patients and their caregivers through treatment with LYTGOBI.**

## SELECTED IMPORTANT SAFETY INFORMATION

## WARNINGS AND PRECAUTIONS (continued)

- **Ocular Toxicity (continued):** 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.

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# Taiho Oncology Patient Support™ contributes to the care they need

Taiho Oncology Patient Support™ offers personalized services to help give patients, caregivers, and healthcare professionals access to Taiho Oncology products. This includes insurance coverage determination and help with medication affordability.

For more information, please visit or refer patients to **TaihoPatientSupport.com.**

TAIHO ONCOLOGY PATIENT SUPPORT™
*Supporting your treatment journey.*

### Meeting the access needs of your patients

Getting patients access to their medicine is an important step. Taiho Oncology Patient Support strives to make this process as simple as possible.


### Taiho Oncology Patient Support can assist with:

- **Insurance Coverage Support***
  - Benefits investigation, prior authorization assistance, and appeals assistance if needed
  - Coordination of prescriptions with pharmacies
- **Personalized Nurse Support†**
  - One-on-one nurse educational support for patients, available via opt-in
- **Patient Affordability Assistance**
  - $0 Co-pay enrollment for eligible commercially insured patients
  - Patient assistance program designed to provide free medication to eligible patients who are uninsured or underinsured
  - Referrals to third-party foundations for co-pay or other assistance based on eligibility and additional criteria
  - Referrals to Medicare Part D Low-Income Subsidy (LIS)/Extra Help Program

*Visit TaihoPatientSupport.com to see full eligibility criteria.
†If selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about LYTGOBI treatment.

LYTGOBI®
(futibatinib) tablets 4 mg

LYTGOBI®
(futibatinib) tablets 4 mg

For more information about treatment with LYTGOBI® (futibatinib) tablets, visit **LYTGOBI.com.**

For financial support or help with insurance, visit **TaihoPatientSupport.com** or call **1-844-TAIHO-4U** (1-844-824-4648) Monday to Friday, 8 am to 8 pm ET.

LYTGOBI is indicated for the treatment of patients with previously treated locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions as detected by an FDA-approved test.

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).[1]

## LYTGOBI can provide

# The power you want. The care patients need.

- An approved irreversibly binding *FGFR* inhibitor[1-3]
- **42%** overall response rate[1]
  - 95% CI: 32%, 52%; N=103
- **9.7** months median duration of response[1]
  - 95% CI: 7.6, 17.1; N=103
- Continuous, once-daily oral dosing[1]
- No Grade 4 or 5 reactions occurred, among the most common (≥15%) ARs[1]*
- Use of LYTGOBI is associated with the following serious risks: ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity[1]

*In the FOENIX-CCA2 trial.[5]

- Serious adverse reactions occurred in 39% of patients receiving LYTGOBI. Serious adverse reactions in ≥2% of patients who received LYTGOBI included pyrexia (3.9%), gastrointestinal hemorrhage (3.9%), ascites (2.9%), musculoskeletal pain (2.9%), and bile duct obstruction (2.9%)[1]
- The most common (≥20%) adverse reactions were nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, and vomiting[1]

**References: 1.** LYTGOBI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2022. **2.** Kalyukina M, Yosaatmadja Y, Middleditch MJ, Patterson AV, Smaill JB, Squire CJ. TAS-120 cancer target binding: defining reactivity and revealing the first fibroblast growth factor receptor 1 (FGFR1) irreversible structure. *ChemMedChem.* 2019;14(4):494–500. **3.** Sootome H, Fujita H, Ito K, et al. Futibatinib is a novel irreversible FGFR 1-4 inhibitor that shows selective antitumor activity against FGFR-deregulated tumors. *Cancer Res.* 2020;80(22):4986-4997. **4.** Bridgewater JA, Meric-Bernstam F, Hollebecque A, et al. Efficacy and safety of futibatinib in intrahepatic cholangiocarcinoma harboring *FGFR2* fusions/rearrangements: subgroup analyses of a phase 2 study (FOENIX-CCA2). Poster presented at the European Society of Medical Oncology Virtual Congress; September 19-21, 2020. **5.** Goyal L, Meric-Bernstam F, Hollebecque A, et al. Futibatinib for FGFR2-Rearranged Intrahepatic Cholangiocarcinoma. *N Engl J Med.* 2023;388(3):228-239. doi:10.1056/NEJMoa2206834 **6.** Goyal L, Meric-Bernstam F, Hollebecque A, et al. Primary results of phase 2 FOENIX-CCA2: the irreversible FGFR1–4 inhibitor futibatinib in intrahepatic cholangiocarcinoma with *FGFR2* fusions/rearrangements. Abstract presented at the American Association for Cancer Research Annual Meeting; April 10-15, 2021, and May 17-21, 2021. Abstract CT010. **7.** Goyal L, Meric-Bernstam F, Hollebecque A, et al. Updated results of the FOENIX-CCA2 trial: efficacy and safety of futibatinib in intrahepatic cholangiocarcinoma (iCCA) harboring *FGFR2* fusions/rearrangements. Meeting abstract 4009. *J Clin Oncol.* 2022;40(16 suppl). doi:abs/10.1200/JCO.2022.40.16_suppl.4009. **8.** National Cancer Institute. National Institutes of Health. Chemotherapy and You. September 2018. NIH publication no. 18-7157. National Cancer Institute website. https://www.cancer.gov/publications/patient-education/chemotherapy-and-you.pdf. Accessed December 10, 2021.

**Please see Important Safety Information throughout and full Prescribing Information in pocket or at LYTGOBI.com/PI.**



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