For patients taking LYTGOBI® tablets

Specialist referral forms: eye, skin, hair, and nails

Given the potential for eye, skin, hair, and nail toxicity in patients treated with LYTGOBI, this resource provides referral tear sheets for patients to present to appropriate specialists (ophthalmologist, optometrist, dermatologist, podiatrist, etc). These sheets should be used both before and during treatment as needed. Consider advising patients to schedule specialist appointments at the start of treatment, as wait times can be several months.

Prior to initiation of therapy, patients are required to undergo a comprehensive ophthalmological examination including optical coherence tomography of the macula, every 2 months for the first 6 months, and every 3 months thereafter. For onset of visual symptoms, refer patients for ophthalmological evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of LYTGOBI.

CLICK THESE LINKS

To learn about LYTGOBI efficacy results

To contact your local OAM to request more referral pads

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).

Please see accompanying full Prescribing Information at LYTGOBI.com/PI.

LYTGOBI®
(futibatinib) tablets 4 mg

Established safety with LYTGOBI®

Safety considerations[1]

- Among the most common (≥15%) adverse reactions (ARs) experienced by patients receiving LYTGOBI in FOENIX-CCA2, no Grade 4 or 5 reactions occurred
- Clinically relevant ARs occurring in ≤15% of patients included retinal pigment epithelial detachment (RPED, 9%)
- **Use of LYTGOBI is associated with the following serious risks: ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity**

ARs (≥15%) in patients receiving LYTGOBI in the FOENIX-CCA2 trial

LYTGOBI (N=103)		
ARs	**All Grades[a] (%)**	**Grade 3 (%)**
Skin and subcutaneous tissue disorders		
Nail toxicity[b]	47	1.9
Alopecia	34	0
Dry skin	29	0
Palmar-plantar erythrodysesthesia syndrome	21	4.9
Gastrointestinal disorders		
Constipation	39	0
Diarrhea[c]	39	1
Dry mouth	35	0
Stomatitis[d]	30	6
Abdominal pain[e]	30	2.9
Nausea	24	1.9
Vomiting[f]	20	1

LYTGOBI (N=103)		
ARs	**All Grades[a] (%)**	**Grade 3 (%)**
General disorders		
Fatigue[g]	37	8
Metabolism and nutrition disorders		
Decreased appetite	23	2.9
Musculoskeletal and connective tissue disorder		
Musculoskeletal pain[h]	43	3.9
Arthralgia[i]	25	0
Eye disorders		
Dry eye[j]	25	1
Nervous system disorders		
Dysgeusia[k]	25	0
Infections		
Urinary tract infection[l]	23	2.9
Investigations		
Weight decreased	18	3.9

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

Please see accompanying full Prescribing Information at LYTGOBI.com/PI.

LYTGOBI®
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Established safety with LYTGOBI® (cont'd)

Select laboratory abnormalities (≥10%) worsening from baseline in patients receiving LYTGOBI in the FOENIX-CCA2 trial[1]

LYTGOBI (N=103)		
Laboratory Abnormality[a]	**All Grades[b] (%)**	**Grades 3 or 4 (%)**
Hematology		
Decreased hemoglobin	52	6
Decreased lymphocytes	46	10
Decreased platelets	42	1
Decreased leukocytes	33	1.1
Decreased neutrophils	31	1.6
Chemistry		
Increased phosphate[c]	97	39
Increased creatinine[d]	58	0
Increased glucose	52	4.9
Increased calcium	51	1.2
Decreased sodium	51	15
Decreased phosphate	50	20
Increased alanine aminotransferase	50	7
Increased alkaline phosphatase	47	4.9
Increased aspartate aminotransferase	46	13
Decreased albumin	31	2.4
Increased creatine kinase	31	5
Increased bilirubin	28	0
Decreased glucose	25	0
Decreased potassium	22	2.1
Increased potassium	16	2
Coagulation		
Increased activated partial thromboplastin time	36	8
Increased prothrombin international normalized ratio	25	0

NCI CTCAE=National Cancer Institute common terminology criteria for adverse events.

[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.

Please see accompanying full Prescribing Information at LYTGOBI.com/PI.

LYTGOBI® (futibatinib) tablets 4 mg

EYE SPECIALIST REFERRAL FORM

ONCOLOGIST TO FILL OUT

Patient Name: _____ **Date:** _____ /_____ /_____

Physician Name: _____

Practice: _____ **Contact Number:** _____

Fax Number: _____ **Email:** _____

LYTGOBI (futibatinib) tablets Start Date: _____ /_____ /_____

Reason for referral:

- ☐ **Prior to initiation of LYTGOBI**, 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
- ☐ **Patient is being treated with LYTGOBI** for cholangiocarcinoma harboring fibroblast growth factor receptor 2 (*FGFR2*) gene fusions or other rearrangements. Patients on *FGFR* inhibitors can develop eye and vision conditions, including Retinal Pigment Epithelial Detachment (RPED)

Symptoms (checklist):

- ☐ Dry or inflamed eyes
- ☐ Inflamed cornea (front part of the eye)
- ☐ Increased tears
- ☐ Blurred vision
- ☐ Visual floaters
- ☐ Other: _____

First onset of symptoms: _____

Notes: _____

_____

Other Medications: _____

SIGN HERE _____

Physician Signature

LYTGOBI®
(futibatinib) tablets 4 mg

Please see Important Safety Information on the next page.

INDICATIONS

What is LYTGOBI?

LYGTOBI is a prescription medicine that is used to treat adults with bile duct cancer (intrahepatic cholangiocarcinoma) that has spread or cannot be removed by surgery, who have already received a previous treatment, and whose tumor has a certain type of abnormal "FGFR2" gene.

Your healthcare provider will test your cancer for a certain type of abnormal FGFR2 gene and make sure that LYTGOBI is right for you.

It is not known if LYTGOBI is safe and effective in children.

LYTGOBI is approved based on tumor response and duration of response. There are ongoing studies to show if LYTGOBI improves survival or symptoms.

IMPORTANT SAFETY INFORMATION

LYTGOBI may cause serious side effects, including:

- **Eye problems:** Certain eye problems are common with LYTGOBI but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), increased tears, and a disorder of the retina (an internal part of the eye). You will need to see an eye specialist for a complete eye exam before you begin treatment with LYTGOBI, every 2 months for the first 6 months, and every 3 months thereafter during treatment with LYTGOBI.
  - **Tell your healthcare provider right away** if you develop any changes in your vision during treatment with LYTGOBI, including blurred vision, flashes of light, or seeing black spots. You may need to see an eye specialist right away.
  - You should use artificial tears or substitutes, or hydrating or lubricating eye gels during treatment with LYTGOBI to help prevent or treat dry eyes.
- **High phosphate levels in your blood (hyperphosphatemia) and buildup of minerals in different tissues in your body:** Hyperphosphatemia is common with LYTGOBI but can also be serious. High levels of phosphate in your blood may lead to buildup of minerals such as calcium in different tissues in your body. Your healthcare provider will check your blood phosphate levels during treatment with LYTGOBI.
  - Your healthcare provider may prescribe changes in your diet or phosphate-lowering therapy, or change, interrupt, or stop LYTGOBI if needed.
  - **Tell your healthcare provider right away** if you develop any muscle cramps, or numbness or tingling around your mouth.

The most common side effects of LYTGOBI include:

- changes in kidney function blood tests
- increased blood glucose level
- decreased red blood cell, white blood cell, and platelet counts
- increased calcium level in the blood
- decreased sodium and phosphate levels in the blood
- changes in liver function blood tests
- nails separate from the bed or poor formation of the nail; change in the color of nails
- muscle pain
- constipation
- diarrhea
- feeling tired or weak
- changes in tests used to measure your blood clotting time
- dry mouth
- hair loss
- decreased protein level (albumin) in the blood
- mouth sores
- stomach area (abdominal) pain
- dry skin
- decreased glucose and potassium level in the blood
- joint pain
- changes in sense of taste
- dry eye
- nausea
- decrease in appetite
- urinary tract infection
- redness, swelling, peeling or tenderness, mainly on the hands or feet ("hand-foot syndrome")
- vomiting

These are not all the possible side effects of LYTGOBI. For more information, talk to your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

Before you take LYTGOBI, tell your healthcare provider about all of your medical conditions, including if you:

- have vision or eye problems.
- are pregnant or plan to become pregnant. LYTGOBI can harm your unborn baby or cause loss of your pregnancy (miscarriage). You should not become pregnant during treatment with LYTGOBI.

  Females who can become pregnant:

  - Your healthcare provider should do a pregnancy test before you start treatment with LYTGOBI.
  - You should use an effective method of birth control during treatment and for 1 week after your final dose of LYTGOBI. Talk to your healthcare provider about birth control methods that may be right for you.
  - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

  Males with female partners who can become pregnant:

  - You should use effective birth control when sexually active during treatment with LYTGOBI and for 1 week after your last dose of LYTGOBI.
- are breastfeeding or plan to breastfeed. It is not known if LYTGOBI passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of LYTGOBI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LYTGOBI and other medicines may affect each other causing side effects. LYTGOBI may affect the way other medicines work, and other medicines may affect how LYTGOBI works.

Please see full Prescribing Information at LYTGOBI.com/PI.

This page should accompany the referral form on the previous page when printed, emailed, or faxed.

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TAIHO ONCOLOGY

LYTGOBI®
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SKIN, HAIR, NAILS SPECIALIST REFERRAL FORM

ONCOLOGIST TO FILL OUT

Patient Name: _____ **Date:** _____ /_____ /_____

Physician Name: _____

Practice: _____ **Contact Number:** _____

Fax Number: _____ **Email:** _____

LYTGOBI (futibatinib) tablets Start Date: _____ /_____ /_____

Reason for referral:

☐ **Patient is being treated with LYTGOBI** for cholangiocarcinoma harboring fibroblast growth factor receptor 2 (*FGFR2*) gene fusions or other rearrangements. *FGFR* inhibitors have the potential to cause dermatologic side effects that impact skin, nail, and hair health

Symptoms (checklist):

- ☐ Nails separated from the bed
- ☐ Poor formation of the nail
- ☐ Nail discoloration
- ☐ Alopecia
- ☐ Dry skin
- ☐ Redness, swelling, peeling or tenderness, mainly on the hands or feet
- ☐ Other: _____

First onset of symptoms: _____

Notes: _____

_____

Other Medications: _____

SIGN HERE _____

Physician Signature

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INDICATIONS

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LYGTOBI is a prescription medicine that is used to treat adults with bile duct cancer (intrahepatic cholangiocarcinoma) that has spread or cannot be removed by surgery, who have already received a previous treatment, and whose tumor has a certain type of abnormal "FGFR2" gene.

Your healthcare provider will test your cancer for a certain type of abnormal FGFR2 gene and make sure that LYTGOBI is right for you.

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LYTGOBI is approved based on tumor response and duration of response. There are ongoing studies to show if LYTGOBI improves survival or symptoms.

IMPORTANT SAFETY INFORMATION

LYTGOBI may cause serious side effects, including:

- **Eye problems:** Certain eye problems are common with LYTGOBI but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), increased tears, and a disorder of the retina (an internal part of the eye). You will need to see an eye specialist for a complete eye exam before you begin treatment with LYTGOBI, every 2 months for the first 6 months, and every 3 months thereafter during treatment with LYTGOBI.
  - **Tell your healthcare provider right away** if you develop any changes in your vision during treatment with LYTGOBI, including blurred vision, flashes of light, or seeing black spots. You may need to see an eye specialist right away.
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- muscle pain
- constipation
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- feeling tired or weak
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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LYTGOBI and other medicines may affect each other causing side effects. LYTGOBI may affect the way other medicines work, and other medicines may affect how LYTGOBI works.

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TAIHO ONCOLOGY

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INDICATION AND USAGE

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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. 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, 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.
- **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.

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 accompanying full Prescribing Information at LYTGOBI.com/PI.

Reference: 1. LYTGOBI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2024.

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