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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommendations for Cholangiocarcinoma

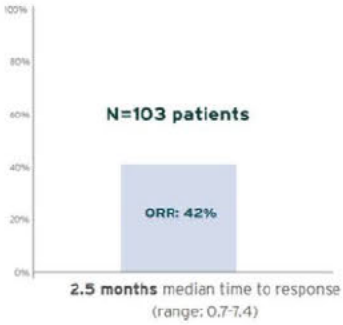
Futibatinib (LYTGOBI) is recommended as a National Comprehensive Cancer Network® (NCCN®) subsequent-line systemic therapy option for unresectable or metastatic intrahepatic or extrahepatic cholangiocarcinoma with *FGFR2* fusions or rearrangements if disease progression[5*†]

Sample‡ treatment algorithm for subsequent-line use for CCA with *FGFR2* fusions or rearrangements:

Primary Therapy for Unresectable and Metastatic Disease	Subsequent-Line Therapy if Disease Progression
Durvalumab + gemcitabine + cisplatin	Futibatinib (LYTGOBI)

*NCCN Category 2A recommendation: based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
†Treatment selection depends on clinical factors, including previous treatment regimen/agent, somatic molecular testing results, and extent of liver dysfunction.
‡These treatment algorithms are examples only; other treatment options are recommended in the NCCN Guidelines.

LYTGOBI demonstrated an overall response rate (ORR) of 42% in patients with previously treated locally advanced or metastatic iCCA[1]



2.5 months median time to response
(range: 0.7-7.4)

The **ORR** for LYTGOBI was
42%
(95% CI: 32%, 52%)
- PR: 42%

Patients experienced a median duration of response (mDoR) of nearly 10 months with LYTGOBI[1]

72% of responders (n=31) had

14% of responders (n=6) had

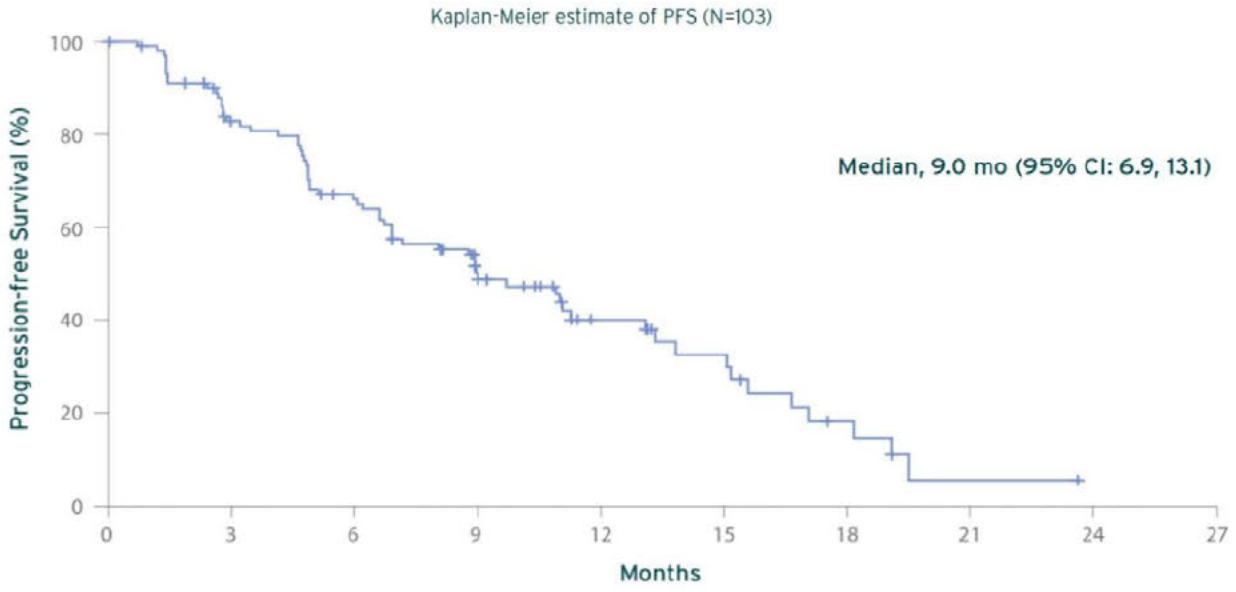
responses that lasted ≥6 months | responses that lasted ≥1 year

FOENIX-CCA2: Additional endpoints

LYTGOBI received accelerated approval from the FDA based on ORR and DoR in a single-arm study[1]

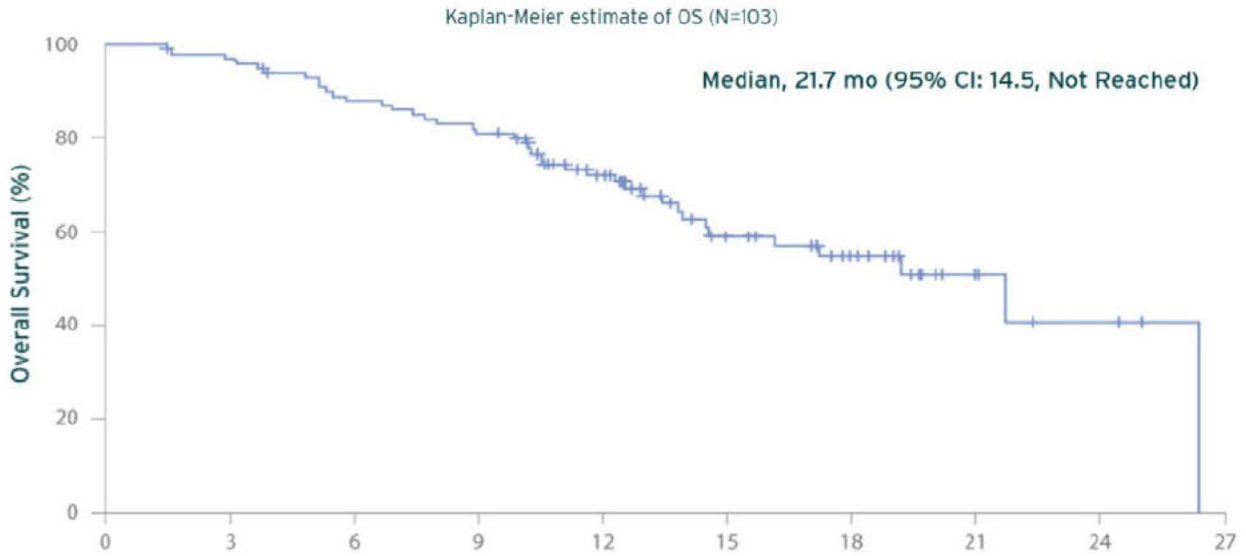
- For this reason, a confirmatory study in cholangiocarcinoma is underway[1]
- Progression-free survival, overall survival, and disease control rate were prespecified secondary endpoints that were studied in FOENIX-CCA2 and that are not reflected in the full Prescribing Information[2]
- Due to potential 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)[2,3]



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

Overall survival (OS)[2,3]



Months

At risk	103	99	88	81	55	31	21	6	3	0
Censored	–	1	2	0	18	16	8	14	2	2

- At the time of data cutoff: Median follow-up was 17.1 months; the OS data were not mature; during the study, 40 patients (39%) died following treatment discontinuation with the majority (90%) dying from disease progression.[2,3]

Disease control rate (DCR) (n=103)[2,3a]

- FOENIX-CCA2 was a single-arm study[2]
  - In this setting, the DCR results may reflect the natural history of cholangiocarcinoma in an individual patient, rather than the direct effect of treatment

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

Supplementary results

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[2,4]:

- ORR of 41.7%
- DCR of 82.5%
- median DoR of 9.5 months
- median PFS of 8.9 months
- 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.

See how LYTGOBI was studied in a clinical trial

View the safety profile of LYTGOBI

Learn about LYTGOBI dosing

PREVIOUS PAGE
← Study Design

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Safety Profile →

CI=confidence interval; DoR=duration of response; iCCA=intrahepatic cholangiocarcinoma; mo=months; PR=partial response.

References:

1. LYTGOBI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2024. **2.** Goyal L, Meric-Bernstam F, Hollebecque A, et al. Futibatinib for *FGFR2*-Rearranged Intrahepatic Cholangiocarcinoma. *N Engl J Med*. 2023;388(3):228-239. **3.** 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: American Association for Cancer Research Annual Meeting; April 10-15, 2021, and May 17-21, 2021. Abstract CT010. **4.** 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. Abstract presented at ASCO Annual Meeting 2022. Abstract 4009. *J Clin Oncol*. 2022;40(16 suppl). **5.** Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers. V.4.2024.* © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed September 10, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.