

Article details



Title of article

FIGHT-302: First-line pemigatinib vs gemcitabine + cisplatin for advanced cholangiocarcinoma with *FGFR2* rearrangements



Authors

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Article URL

<https://www.futuremedicine.com/doi/10.2217/fo-2020-0429>



Trial registration number

NCT03656536

432 patients

Target enrollment: 432 patients (currently recruiting)

Study start date: December 2018



Study procedures: Radiographic tumor assessments (CT/MRI) are performed at baseline, every 9 weeks (every 3 cycles), starting from cycle 3, and until progression is noted by the central reviewer. Adverse events are graded and recorded per the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0. Quality of life is assessed at regular intervals throughout the study

Objectives/rationale



Primary objective

Evaluate the efficacy of pemigatinib versus gemcitabine plus cisplatin in the first-line treatment of patients with cholangiocarcinoma with *FGFR2* rearrangements



Secondary key objectives

Further evaluate the efficacy, safety and tolerability of pemigatinib and the impact of treatment on health-related quality of life

Study design and treatment



Global



Phase III



Open-label



Randomized



Active-controlled



Multicenter

Screening & enrollment:

- Age \geq 18 years
- Histologically confirmed CCA, unresectable and/or metastatic
- No prior systemic treatment
- Documented *FGFR2* rearrangement
- ECOG PS \leq 1



Pemigatinib (13.5 mg QD)



Gemcitabine (1000 mg/m²) + Cisplatin (25 mg/m²)
Day 1, 8 of a 3-week cycle for up to 8 cycles

Randomization 1:1

PD: Discontinue treatment
Follow-up every 12 weeks for survival

CR/PR/SD: Continue treatment & assessment every 3 cycles

PD: Discontinue treatment & assess for eligibility for crossover to pemigatinib

CR/PR/SD: Continue treatment & assessment every 3 cycles

Disease assessment at cycle 3

PD

PD

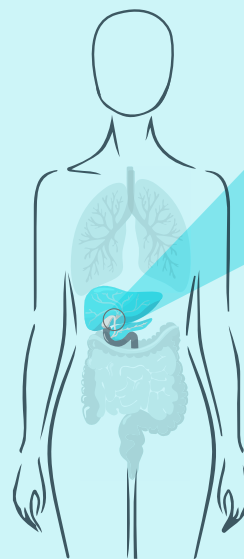
Eligible: Crossover to pemigatinib as second-line treatment; same disease assessment schedule as first-line

Not eligible: Follow-up every 12 weeks for survival

Patients who discontinue due to an adverse event or reason other than PD will continue to have disease assessments until disease progression or death, whichever occurs first

Key eligibility criteria

Inclusion



18+

Men and women aged 18 years or older



Histologically confirmed cholangiocarcinoma that is previously untreated and considered unresectable and/or metastatic



Radiographically measurable or evaluable disease by CT or MRI per RECIST v1.1



Documented *FGFR2* rearrangement

\leq 1

ECOG performance status \leq 1

Exclusion



Corneal/retinal disorders



Abnormal calcium-phosphate homeostasis

Outcome measures/endpoints



Primary endpoint
PFS



Secondary endpoints: ORR, OS, DOR, DCR, safety and tolerability, and health-related quality of life

Glossary

CCA: Cholangiocarcinoma; CR: Complete response; CT: Computed tomography; DCR: Disease control rate; DOR: Duration of response; ECOG: Eastern Cooperative Oncology Group; MRI: Magnetic resonance imaging; ORR: Objective response rate; OS: Overall survival; PD: Progressive disease; PFS: Progression-free survival; PR: Partial response; QD: Once daily; RECIST: Response Evaluation Criteria in Solid Tumors; SD: Stable disease