



A Phase III, Randomized, Controlled, Global Multicenter Study to Evaluate the Efficacy and Safety of Oral Tinengotinib versus Physician s Choice in Subjects with Fibroblast Growth Factor Receptor (FGFR)-altered, Chemotherapy- and FGFR Inhibitor-Refractory/Relapsed Cholangiocarcinoma (FIRST-308)

Status: Recruiting

# Eligibility Criteria

Sex: Male or Female

**Age Group:** 18 years and over This study is NOT accepting healthy

volunteers

#### Inclusion Criteria:

- adenocarcinoma of biliary origin (bile ducts) that can't be surgically removed or is metastatic (spread to other areas of the body) - cancer has FGFR2 fusion/rearrangement gene status - received at least one line of prior chemotherapy and one FDA approved FGFR inhibitor - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

### **Exclusion Criteria:**

- received two or more FGFR inhibitors, either approved or investigational drugs - brain or central nervous system (CNS) metastases - presence of another cancer that requires treatment - uncontrolled hypertension (blood pressure of ≥ 150 mm Hg systolic and/or ≥ 90 mm Hg diastolic despite treatment with antihypertensive medications)

### Conditions & Interventions

### Interventions:

Drug: Physician's Choice, Drug: Tinengotinib 10 mg, Drug: Tinengotinib 8 mg

Conditions:

Cancer

Keywords:

Cholangiocarcinoma

## More Information

**Description:** The main purpose of this study is to learn how well tinengotinib works and how safe tinengotinib is compared with the study doctor's choice of chemotherapy treatment. The purpose of Part A of the study will be to determine the best dose of tinengotinib to use in Part B of the study. The purpose of Part B is to learn more about how well tinengotinib works and how safe it is compared with the study doctor's choice of treatment.

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Phase: PHASE3

IRB

Number: STUDY00021600

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