

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.

Study Contact: Samantha Schommer - schom217@umn.edu

Principal Investigator: Edward Greeno, M.D.

Phase: PHASE3

IRB

Number: STUDY00021600

Thank you for choosing StudyFinder. Please visit <http://studyfinder.umn.edu> to find a Study which is right for you and contact sfinder@umn.edu if you have questions or need assistance.