Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Who Failed Previous Therapy

This study is currently recruiting participants. (see Contacts and Locations)

Verified May 2017 by Incyte Corporation

Sponsor:
Incyte Corporation

Information provided by (Responsible Party):
Incyte Corporation

ClinicalTrials.gov Identifier:
NCT02924376

First received: October 4, 2016
Last updated: May 5, 2017
Last verified: May 2017
History of Changes

Purpose

The purpose of this study is evaluate the efficacy of **INCB**054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma with FGFR2 translocation who have failed at least 1 previous treatment.

Condition	Intervention	Phase
Cholangiocarcinoma	Drug: **INCB**054828	Phase 2

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Masking: No masking
Primary Purpose: Treatment

Official Title: A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of **INCB**054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy

Resource links provided by NLM:

Genetics Home Reference related topics: cholangiocarcinoma

U.S. FDA Resources

Further study details as provided by Incyte Corporation:

Primary Outcome Measures:

- Objective response rate (ORR) in subjects with FGFR2 translocations based on RECIST v1.1 [Time Frame: Every 6 weeks for the first 2 cycles and every 9 weeks thereafter through end of treatment, up to 6 months.]

  ORR defined as the proportion of subjects who achieved a complete response (disappearance of all target lesions) or a partial response (≥ 30% decrease in the sum of the longest diameters of target lesions) based on RECIST v1.1.

Secondary Outcome Measures:

- ORR in subjects with FGF/FGFR alterations other than FGFR2 translocations, all subjects with FGF/FGFR alterations, and subjects negative for FGF/FGFR alterations, based on RECIST v1.1 [Time Frame: Every 6 weeks for the first 2 cycles and every 9 weeks thereafter through end of treatment, up to 6 months]

  ORR defined as the proportion of subjects who achieved a complete response (disappearance of all target lesions) or a partial response (≥ 30% decrease in the sum of the longest diameters of target lesions) based on RECIST v1.1.

- Progression-free survival based on RECIST v1.1 [Time Frame: Every 6 weeks for the first 2 cycles and every 9 weeks thereafter through end of treatment, up to 6 months.]

  Progression-free survival defined as the time from the first day of taking study drug to death or disease progression by RECIST v1.1.

- Safety and tolerability of **INCB**054828 as assessed by the frequency, duration, and severity of adverse events [Time Frame: From screening through 30-35 days after end of treatment, up to 6 months.]

Estimated Enrollment: 100
Study Start Date: October 2016
Estimated Study Completion Date: December 2018
Estimated Primary Completion Date: April 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Cohort A **INCB**054828 **INCB**054828 in subjects with FGFR2 translocation	Drug: **INCB**054828 **INCB**054828 once daily
Experimental: Cohort B **INCB**054828 **INCB**054828 in subjects with other FGF/FGFR alterations	Drug: **INCB**054828 **INCB**054828 once daily
Experimental: Cohort C **INCB**054828 **INCB**054828 in subjects negative for FGF/FGFR alteration	Drug: **INCB**054828 **INCB**054828 once daily

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Histologically or cytologically confirmed cholangiocarcinoma.
- Radiographically measurable or evaluable disease per RECIST v1.1.
- Tumor assessment for FGF/FGFR gene alteration status.
- Documented disease progression after at least 1 line of prior systemic therapy.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
- Life expectancy ≥ 12 weeks.

Exclusion Criteria:

- Prior receipt of a selective FGFR inhibitor.
- History of and/or current evidence of ectopic mineralization/calcification, including but not limited to soft tissue, kidneys, intestine, myocardia, or lung, excepting calcified lymph nodes and asymptomatic arterial or cartilage/tendon calcifications.
- Current evidence of clinically significant corneal or retinal disorder confirmed by ophthalmologic examination.
- Use of any potent CYP3A4 inhibitors or inducers within 14 days or 5 half-lives, whichever is shorter, before the first dose of study drug. Topical ketoconazole will be allowed.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02924376

Contacts

Contact: Incyte Corporation Call Center 1.855.463.3463

Show 36 Study Locations

Sponsors and Collaborators

Incyte Corporation

Investigators

Study Director: Luis Féliz Vinas, MD Incyte Corporation

More Information

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ClinicalTrials.gov Identifier:	NCT02924376 History of Changes
Other Study ID Numbers:	**INCB 54828-202**
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Keywords provided by Incyte Corporation:
Cholangiocarcinoma
fibroblast growth factor (FGF)
fibroblast growth factor receptor (FGFR)
FGF/FGFR alterations

Additional relevant MeSH terms:

Cholangiocarcinoma	Neoplasms, Glandular and Epithelial
Adenocarcinoma	Neoplasms by Histologic Type
Carcinoma	Neoplasms

ClinicalTrials.gov processed this record on May 17, 2017