Trial record **2 of 5** for: INCB054828

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A Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Urothelial Carcinoma

ClinicalTrials.gov Identifier: NCT02872714

Recruitment Status: Recruiting
First Posted: August 19, 2016
Last Update Posted: January 17, 2018

See Contacts and Locations

Sponsor:
Incyte Corporation

Information provided by (Responsible Party):
Incyte Corporation

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
The purpose of this study is to evaluate the overall response rate (ORR) of **INCB054828** as a monotherapy in the treatment of metastatic or surgically unresectable urothelial carcinoma harboring FGF/FGFR alterations.

Condition or disease	Intervention/treatment	Phase
UC (Urothelial Cancer)	Drug: **INCB054828**	Phase 2

Study Design

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Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	140 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment

Official Title:	A Phase 2, Open-Label, Single-Agent, Multicenter Study to Evaluate the Efficacy and Safety of **INCB054828** in Subjects With Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations
Study Start Date:	August 2016
Estimated Primary Completion Date:	December 2018
Estimated Study Completion Date:	January 2019

Resource links provided by the National Library of Medicine

Genetic and Rare Diseases Information Center resources: Transitional Cell Carcinoma

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Cohort A **INCB054828** **INCB054828** in subjects with FGFR3 mutations or fusions	Drug: **INCB054828** **INCB054828** once a day by mouth for 2 consecutive weeks and 1 week off therapy
Experimental: Cohort B **INCB054828** **INCB054828** in subjects with other FGF/FGFR alterations	Drug: **INCB054828** **INCB054828** once a day by mouth for 2 consecutive weeks and 1 week off therapy

Outcome Measures

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Primary Outcome Measures:

1. Objective response rate (ORR) in subjects with FGFR3 mutations based on RECIST v1.1 [Time Frame: Every 9 weeks throughout the study, up to approximately 6 months]

   Defined as the proportion of subjects with best response (complete response or partial response) by RECIST v1.1.

Secondary Outcome Measures:

1. Safety and tolerability of **INCB054828** 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 approximately 6 months]
2. Overall response rate (ORR) measuring the efficacy of **INCB054828** in subjects with advanced/metastatic or surgically unresectable urothelial cancer with different molecular subgroups [Time Frame: From screening through 30-35 days after end of treatment, up to approximately 6 months]
3. Progression-free survival (PFS) based on RECIST v1.1 [Time Frame: Every 9 weeks throughout the study, up to approximately 6 months]

   Defined as number of days from the first day of taking study drug dose to the earlier of death or disease progression by RECIST v1.1 as assessed by the central radiographic review committee

4. Duration of response [Time Frame: Every 9 weeks throughout the study, up to approximately 6 months]

   Defined as the number of days from the date of the first confirmed response to the date of the first documented evidence of disease progression or death.

Eligibility Criteria

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Information from the National Library of Medicine

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, Learn About Clinical Studies.

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

Criteria

Inclusion Criteria:

- Histologically documented metastatic or surgically unresectable urothelial carcinoma; may include primary site from ureters, upper tract, renal pelvis, and bladder.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
- Life expectancy ≥ 12 weeks.
- Radiographically measurable per RECIST v1.1.
- Documented FGF/FGFR alteration and have either 1a) failed at least 1 previous treatment for their metastatic or surgically unresectable urothelial carcinoma (ie, chemotherapy, immunotherapy) or 1b) have not received chemotherapy due to poor ECOG status or 2) have insufficient renal function.

Exclusion Criteria:

- Prior receipt of a selective FGFR inhibitor.
- 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.
- Inability or unwillingness to swallow INCB054828 or significant gastrointestinal disorder(s) that could interfere with the absorption, metabolism, or excretion of INCB054828.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02872714***

Contacts

Contact: Incyte Corporation Call Center 1.855.463.3463

Show 75 Study Locations

Sponsors and Collaborators

Incyte Corporation

Investigators

Study Director: Ekaterine Asatiani, MD Incyte Corporation

More Information

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Responsible Party:	Incyte Corporation
ClinicalTrials.gov Identifier:	NCT02872714 History of Changes
Other Study ID Numbers:	INCB 54828-201
First Posted:	August 19, 2016 Key Record Dates
Last Update Posted:	January 17, 2018
Last Verified:	January 2018

Keywords provided by Incyte Corporation:
Urothelial carcinoma
fibroblast growth factor (FGF)
fibroblast growth factor receptor (FGFR)
FGF/FGFR alterations

Additional relevant MeSH terms:
Carcinoma
Carcinoma, Transitional Cell
Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Neoplasms