INCB161734 (KRASG12D Inhibitor)[1,2]

Population: patients with advanced or metastatic solid tumors with *KRAS*G12D mutation

Phase 1
ClinicalTrials.gov ID: NCT06179160
Study ID: INCB161734-101

Adults with advanced or metastatic solid tumors

N≈710

Part 1

INCB161734 monotherapy[1]

Part 1a: Dose escalation[a]

RDE(s)

Part 1c: PD cohort

Part 1d: Food effect cohort

Part 1b: Dose expansion[a]

Part 2

INCB161734 combinations[2]

- Cetuximab combo: PDAC or CRC
- Retifanlimab-dlwr combo: PDAC, CRC, or NSCLC
- GEMNabP combo: PDAC
- mFOLFIRINOX combo: PDAC
- Cetuximab + chemotherapy combo: CRC
- INCA33890[b] combo: PDAC or CRC

Part 2a: Dose escalation[a,c]

RDE(s)

Part 2b: Dose expansion[a,c]

[a] INCB161734 will be administered at the protocol-defined dose based on cohort assignment. [b] TGFβR2×PD-1–directed bispecific antibody.
[c] Cetuximab, retifanlimab-dlwr, GEMNabP, and mFOLFIRINOX will be administered at protocol-defined doses.

PRIMARY ENDPOINTS

Dose-limiting toxicities

Incidence of TEAEs

Incidence of TEAEs leading to dose modification or discontinuation

SECONDARY ENDPOINTS

PK parameters

ORR

DCR

DOR

SELECT INCLUSION CRITERIA

- ≥18 years of age with locally advanced or metastatic solid tumors with *KRAS*G12D mutation
- Part 1 monotherapy and part 2 cetuximab, retifanlimab-dlwr, and INCA33890 combo groups only: disease progression with prior standard treatment, intolerance of or ineligibility for standard treatment, or no available standard treatment to improve disease outcome
- Cohort-specific requirements as defined in the protocol
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

SELECT EXCLUSION CRITERIA

- Prior treatment with any KRASG12D inhibitor
- Known additional invasive malignancy within 1 year of the first dose of study drug

The efficacy and safety of the investigational compounds discussed have not been established. There is no guarantee that these compounds will become commercially available for the uses under investigation.

For more information, visit **IncyteClinicalTrials.com** or contact us at **1-855-4MED-INFO (855-463-3463)** or **clintrials@incyte.com**

A copy of this panel can be accessed using the QR code:

Combo, combination; CRC, colorectal cancer; DCR, disease control rate; DOR, duration of response; GEMNabP, nab-paclitaxel + gemcitabine; KRAS, KRAS proto-oncogene, GTPase; mFOLFIRINOX, modified leucovorin calcium, fluorouracil, irinotecan hydrochloride, and oxaliplatin; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD, pharmacodynamics; PD-1, programmed cell death 1 protein; PDAC, pancreatic ductal adenocarcinoma; PK, pharmacokinetics; RDE, recommended dose for expansion; TEAE, treatment-emergent adverse event; TGFβR2, transforming growth factor β receptor 2.

1. ClinicalTrials.gov. Accessed Dec 2025. https://clinicaltrials.gov/study/NCT06179160 2. Desai J, et al. ESMO 2025. Presentation 9160.

This information is current as of December 22, 2025.