

Protocol CINC280

Clinical Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type Advanced Non-small Cell Lung Cancer.

This is the trial summary as assessed on clinicaltrials.gov on 14/05/2019

Minor changes in the protocol may occur. You can check this on this direct link:

<https://clinicaltrials.gov/ct2/show/NCT02414139?term=CINC280A2201&rank=1>

Trial Design :

A phase II study to evaluate antitumor activity of oral cMET inhibitor INC280 in adult patients with EGFR wild-type, advanced non-small cell lung cancer (NSCLC) as measured by overall response rate (ORR). The study will also evaluate safety and pharmacokinetics of INC280.

Inclusion Criteria:

Stage IIIB or IV NSCLC (any histology) at the time of study entry

Histologically or cytologically confirmed diagnosis of NSCLC that is:

1. EGFR wt as per patient standard of care by a validated test
2. AND ALK-negative rearrangement as part of the patient standard of care by a validated test
3. AND (by central assessment) either:
 - Cohort 1: Pre-treated patients with cMET GCN ≥ 6 or
 - Cohort 2: Pre-treated patients with cMET GCN ≥ 4 and < 6 , or
 - Cohort 3: Pre-treated patients with cMET GCN < 4 , or
 - Cohort 4: Pre-treated patients with cMET mutations regardless of cMET GCN, or
 - Cohort 5: Treatment-naïve patients with cMET dysregulation
 - Cohort 6: Pre-treated patients with either cMET GCN ≥ 10 without cMET mutations or cMET mutations regardless of cMET GCN, or
 - Cohort 7: Treatment-naïve patients with cMET mutations regardless of cMET GCN

To be eligible for Cohort 6, patients must have failed one prior line of systemic therapy for advanced/metastatic disease

To be eligible for Cohort 5 and Cohort 7, patients must not have received any systemic therapy for advanced/metastatic disease

At least one measurable lesion as defined by RECIST 1.1

Patients must have recovered from all toxicities related to prior anticancer therapies to grade ≤ 1 (CTCAE v 4.03). Patients with any grade of alopecia are allowed to enter the study.

Patients must have adequate organ function

ECOG performance status (PS) of 0 or 1

Details and other protocol-defined inclusion criteria may apply.

Exclusion Criteria:

Prior treatment with crizotinib, or any other cMET or HGF inhibitor

Patients with characterized EGFR mutations that predict sensitivity to EGFR therapy, including, but not limited to exon 19 deletions and exon 21 mutations

Patients with characterized ALK-positive rearrangement

Clinically significant, uncontrolled heart diseases.

Patients receiving treatment with medications that cannot be discontinued at least 1 week prior to first INC280 treatment and for the duration of the study:

Strong inducers of CYP3A4

Impairment of GI function or GI disease that may significantly alter the absorption of INC280

Patients receiving treatment with any enzyme-inducing anticonvulsant

Applicable to Cohorts 1-4 and Cohort 6 only: Previous anti-cancer and investigational agents within 4 weeks or $\leq 5 \times$ half-life of the agent (whichever is longer) before first dose

Pregnant or nursing women

Women of child-bearing potential, unless they are using highly effective methods of contraception

Sexually active males unless they use a condom during intercourse

Presence or history of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis

Other protocol-defined exclusion criteria may apply.