Protocol : Capmatinib CINC280A2201

A phase II, multicenter, four-cohort study of oral cMET inhibitor INC280 in adult patients with EGFR wild-type, advanced non-small cell lung cancer (NSCLC) who have received one or two prior lines of systemic therapy for advanced/metastatic disease.

This is the trial summary as assessed on clinicaltrials.gov on 07/04/2016.

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

https://clinicaltrials.gov/ct2/results?term=CINC280A2201&Search=Search

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) after one or two prior lines of systemic therapy for advanced/metastatic disease 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:

EGFR wt as per patient standard of care by a validated test

AND ALK-negative rearrangement as part of the patient standard of care by a validated test

AND (by central assessment) either:

Cohort 1: cMET GCN $\geq$ 6, or

Cohort 2: cMET GCN $\geq$4 and < 6, or

Cohort 3: cMET GCN < 4, or

Cohort 4: Patients with cMET mutations regardless of cMET GCN

Patients must have received one or two prior lines of systemic therapy

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 $\leq$ 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 and moderate inhibitors of CYP3A4

Strong inducers of CYP3A4

Proton pump inhibitors (PPI)

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

Patients receiving treatment with any enzyme-inducing anticonvulsant.

Previous anti-cancer and investigational agents.

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

Other protocol-defined exclusion criteria may apply