Protocol CAPMATINIB / SPARTALIZUMAB

A phase II, multicenter, randomized, two-arm study of capmatinib (INC280, an oral MET inhibitor) and spartalizumab (PDR001, a PD-1 inhibitor) combination therapy versus docetaxel in pretreated adult patients with EGFR wild-type, ALK rearrangement negative locally advanced/metastatic non-small cell lung cancer.

This is the trial summary as assessed on clinicaltrials.gov on 5/12/2018

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

https://clinicaltrials.gov/ct2/show/NCT03647488?term=number%3A+2018-001420-19&rank=1

Trial Design :

This is a clinical research study and the purpose of the study is to learn whether the combination of the drugs capmatinib plus spartalizumab helps to control lung cancer better compared to a single agent chemotherapy (docetaxel) and whether it is safe when given to patients with NSCLC.

Inclusion Criteria:

Histologically confirmed locally advanced/metastatic (stage IIIB/IV), EGFR wild-type, ALK rearrangement negative, non-small cell lung cancer

Subject has demonstrated progression following one prior platinum doublet and one prior PD-(L)1 checkpoint inhibitor (either alone or in combination, the most recent treatment regimen must have contained a PD-(L)1 checkpoint inhibitor)

Subjects must be candidates for single agent docetaxel

Subjects must have at least one lesion evaluable by RECIST 1.1

Exclusion Criteria:

Prior treatment with a MET inhibitor or HGF (Hepatocyte growth factor) targeting therapy

Any untreated central nervous system (CNS) lesion

Use of any live vaccines against infectious diseases within 12 weeks of initiation of study treatment.

Other protocol-defined inclusion/exclusion criteria may apply.