CINC280A2301 - Novartis

Study of Capmatinib Efficacy in Comparison With Docetaxel in Previously Treated Participants With Non-small Cell Lung Cancer Harboring MET Exon 14 Skipping Mutation

This is the trial summary as assessed on clinicaltrials.gov on 05/10/2020.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT04427072

Trial Design:

Arm	Intervention
Experimental	Capmatinib – 400 mg – BID - orally
Active comparator	Docetaxel – 75mg/m^2 – 3-weekly - IV

Inclusion criteria:

- Stage IIIB/IIIC (not amenable to surgery, radiation or multi modality therapy) or IV NSCLC (according to Version 8 of the American Joint Committee on Cancer (AJCC) Staging Manual) at the time of study entry.
- Histologically or cytologically confirmed diagnosis of NSCLC that is:
    1. EGFR wt. Assessed as part of participant's standard of care by a validated test for EGFR mutations as per local guidelines. The EGFR wt status (for EGFR mutations that predict sensitivity to EGFR therapy, including, but not limited to exon 19 deletions and exon 21 L858R substitution mutations.
    2. AND ALK rearrangement negative. Assessed as part of participant's standard of care by a validated test.
    3. AND has METΔex14 mutation per Novartis-designated central laboratory.
- Mandatory provision of a formalin-fixed, paraffin embedded tumor tissue sample (archival tumor block or slides, or a newly obtained tumor sample)
- Progressed on one or two prior lines of systemic therapy for advanced/metastatic disease (stage IIIB/IIIC [not candidates for surgery, radiation or multi modality therapy] or IV NSCLC) and must be candidates for single agent chemotherapy (docetaxel).
- At least one measurable lesion as defined by RECIST 1.1
- Adequate organ function
- Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1.

Exclusion criteria:

- Prior treatment with any MET inhibitor or HGF-targeting therapy.
- Participants with symptomatic central nervous system (CNS) metastases who are neurologically unstable or have required increasing doses of steroids within the 2 weeks prior to study entry to manage CNS symptoms.
- Participants with known druggable molecular alterations (such as ROS1 translocation or BRAF mutation, etc.) which might be a candidate for alternative targeted therapies as applicable per local regulations and treatment guidelines.

- Presence or history of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis (i.e., affecting activities of daily living or requiring therapeutic intervention).
- Substance abuse, active infection or other severe, acute, or chronic medical or psychotic conditions or laboratory abnormalities that in the opinion of the investigator may increase the risk associated with study participation

Other protocol-defined inclusion/exclusion criteria may apply.