OUR TRIALS

Tepotinib is under clinical investigation in several countries of the world. Safety and efficacy of tepotinib have to be investigated following the respective local regulations and laws. There is no guarantee that tepotinib will be approved in the sought-after indication by the competent health authority in your country.

INSIGHT 2

NOW ENROLLING: **Patients with *MET* amplified advanced or metastatic NSCLC harboring activating *EGFR* mutations and acquired resistance to prior EGFR TKI.[1]**

Visit clinicaltrials.targeting-met.com, or clinicaltrials.gov NCT03940703 for more details.

Purpose of this study

In this phase 2 trial the safety and efficacy of tepotinib, an oral and once-daily MET inhibitor, is investigated in combination with osimertinib in patients with *MET* amplified advanced/metastatic NSCLC harboring activating *EGFR* mutations and acquired resistance to prior EGFR TKI.

Study design

Advanced or metastatic *EGFR*-mutated NSCLC

MET amplification

Acquired resistance to prior EGFR TKI therapy

N = 90*

Tepotinib 500 mg orally once daily** + **Osimertinib** 80 mg orally once daily**

Endpoints

Key endpoints include:

ORR (by independent and investigator review), **DLTs** (safety run-in only), safety, **PFS**, **DOR**, **DC**, **OS**, **HRQOL**, **PK**

Key eligibility criteria

- Histologically confirmed locally advanced or metastatic NSCLC with a documented activating *EGFR* mutation
- *MET* amplification
- Acquired resistance on prior EGFR TKI therapy
- ECOG PS of 0 or 1

Key exclusion criteria

- Patients with symptomatic brain metastases who are neurologically unstable
- Inadequate hematological, liver, renal or cardiac function, or hypertension uncontrolled by standard therapies
- Any unresolved Grade 2 or higher toxicity from previous therapies

*Target enrollment.
**Treatment continues until progression of disease, withdrawal of consent, or development of unacceptable toxicities.

For a full list of all outcome measures, inclusion and exclusion criteria, please visit clinicaltrials.gov NCT03940703.

VISION

NOW ENROLLING: **Patients with advanced or metastatic NSCLC harboring *MET* exon 14 skipping alterations.[2]**

Visit clinicaltrials.targeting-met.com, or clinicaltrials.gov NCT02864992 for more details.

Purpose of this study

In this phase 2, single-arm, multi-cohort trial the safety and efficacy of tepotinib, an oral and once-daily *MET* inhibitor, is investigated in patients with advanced or metastatic NSCLC harboring MET alterations.

Study design

Advanced or metastatic NSCLC

MET exon 14 skipping

First, second or third line of therapy

N ≤280*

Tepotinib 500 mg orally once daily**

Endpoints

Key endpoints include:

ORR (by independent and investigator review), **DOR**, **DC**, **PFS**, **OS**, safety, **HRQOL**

Key eligibility criteria

- Histologically confirmed locally advanced or metastatic NSCLC (all histologies including squamous and sarcomatoid)
- *MET*ex14 skipping alteration (plasma and/or tissue biopsy sample)
- ECOG PS of 0 or 1
- Prior therapy with a checkpoint inhibitor is permitted

Key exclusion criteria

- *EGFR* activating mutations or *ALK* rearrangements that predict response to anti-EGFR/anti-ALK therapy
- Active brain metastases, or brain metastasis as the only measurable lesion
- Prior treatment with other agents targeting the MET pathway

*Target enrollment.
**Treatment continues until progression of disease, withdrawal of consent, or development of unacceptable toxicities.

For a full list of all outcome measures, inclusion and exclusion criteria, please visit clinicaltrials.gov NCT02864992.

References
1. Clinicaltrials.gov. A Study of Tepotinib Plus Osimertinib in Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor (TKI) Relapsed Mesenchymal-epithelial Transition Factor (MET) Amplified Non-small Cell Lung Cancer (NSCLC). https://clinicaltrials.gov/ct2/show/NCT03940703. Last accessed: May 13, 2020.
2. Clinicaltrials.gov. Tepotinib Phase II in Non-small Cell Lung Cancer (NSCLC) Harboring MET Alterations (VISION). https://clinicaltrials.gov/ct2/show/NCT02864992. Last accessed: May 13, 2020.

DC, disease control; DLT, dose limiting toxicity; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EGFR, epidermal growth factor receptor; HRQOL, health-related quality of life; MET, mesenchymal-epithelial transition factor; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; TKI, tyrosine kinase inhibitor.

US/TEP/0520/0016 May 2020