MARIPOSA-2 (Janssen Research & Development)

A Phase 3, Open-Label, Randomized Study of Amivantamab and Lazertinib in Combination with Platinum-Based Chemotherapy Compared with Platinum-Based Chemotherapy in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer After Osimertinib Failure

This is the trial summary as assessed on clinicaltrials.gov on 10/01/2021.

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

https://clinicaltrials.gov/ct2/show/NCT04988295?term=61186372NSC3002&draw=2&rank=1

Trial Design:

The purpose of this study is to assess the efficacy of lazertinib, amivantamab, carboplatin, and pemetrexed (LACP) compared with carboplatin and pemetrexed (CP), in participants with locally advanced or metastatic epidermal growth factor receptor (EGFR) Exon 19del or Exon 21 L858R substitution non-small cell lung cancer (NSCLC) after osimertinib failure.

Experimental: Arm A: LACP (Lazertinib, Amivantamab, Carboplatin, and Pemetrexed)
Participants will receive Lazertinib orally along with Amivantamab, Pemetrexed, and Carboplatin as intravenous (IV) infusion for up to 4 cycles (each cycle consists of 21 days). After 4 cycles, participants will receive Lazertinib, Pemetrexed, and Amivantamab as maintenance until disease progression.

Active Comparator: Arm B: CP (Carboplatin and Pemetrexed)
Participants will receive Pemetrexed in combination with Carboplatin as IV infusion for up to 4 cycles (each cycle consists of 21 days). After 4 cycles, participants will receive Pemetrexed as maintenance until disease progression.

Experimental: Arm C: ACP (Amivantamab, Carboplatin and Pemetrexed)
Participants will receive Amivantamab, Pemetrexed, and Carboplatin as IV infusion for up to 4 cycles (each cycle consists of 21 days). After 4 cycles, participants will receive Amivantamab and Pemetrexed as maintenance until disease progression.

Inclusion criteria:

- Participant must have at least 1 measurable lesion, according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, that has not been previously irradiated
- Participant must have histologically or cytologically confirmed, locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC), characterized at or after the tine of locally advanced metastatic disease diagnosis by either epidermal growth factor receptor (EGFR) Exon 19del or Exon 21 L858R mutation
- A participant with definitively, locally treated brain metastases must be clinically stable and asymptomatic, with or without low-dose corticosteroid treatment (less than or equal to [<=]10 milligrams [mg]) prednisone or equivalent), for at least 14 days prior to randomization
- Participant must have Eastern Cooperative Oncology Group (ECOG) status of 0 or 1

- Any toxicities from prior systemic anticancer therapy must have resolved to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0 Grade 1 or baseline level (except for alopecia [any grade], Grade <= 2 peripheral neuropathy, or Grade <= 2 hypothyroidism stable on hormone replacement)
- A woman of childbearing potential must have a negative serum pregnancy test at screening and within 72 hours of the first dose of study treatment and must agree to further serum or urine pregnancy tests during the study
- Participant must have progressed on or after osimertinib monotherapy as the most recent line of treatment. Osimertinib must have been administered as either the first-line treatment for locally advanced or metastatic disease or in the second- line setting after prior treatment with first- or second-generation EGFR tyrosine kinase inhibitor (TKI). Participants who received either neoadjuvant and/or adjuvant treatment are eligible if progression to locally advanced or metastatic disease occurred at least 12 months after the last dose of such therapy and then the participant progressed on or after osimertinib in the locally advanced or metastatic setting. Treatment with osimertinib must be discontinued at least 8 days (4 half-lives) prior to randomization (that is last dose no later than Day -8)

Exclusion criteria:

- Participant received radiotherapy for palliative treatment of NSCLC less than 14 days prior to randomization
- Participant has active brain metastases not definitively treated with local therapy
- Participant has leptomeningeal disease, or participant has spinal cord compression not definitively treated with surgery or radiation
- Participant has known small cell transformation
- Participant has a medical history of interstitial lung disease (ILD), including drug-induced ILD or radiation pneumonitis