MARIPOSA (Janssen Research & Development)

A Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib in Locally Advanced or Metastatic Non-Small Cell Lung Cancer.

This is the trial summary as assessed on clinicaltrials.gov on 10/12/2020.

Minor changes in the protocol may occur. You can check this on this direct link: https://www.clinicaltrials.gov/ct2/show/NCT04487080

Trial Design:

The purpose of this study is to assess the efficacy of the amivantamab and lazertinib combination, compared with osimertinib, in participants with epidermal growth factor receptor (EGFR) mutation (Exon 19 deletions [Exon 19del] or Exon 21 L858R substitution) positive, locally advanced or metastatic non-small cell lung cancer (NSCLC).

Arm	Intervention
Experimental: Treatment A	Amivantamab IV + Lazertinib 240 mg PO
Active comparator: Treatment B	Osimertinib 80 mg PO + placebo
Experimental: Treatment C	Lazertinib 240 mg PO + placebo

Inclusion criteria:

- Participant must have histologically or cytologically confirmed, locally advanced or metastatic non-small cell lung cancer (NSCLC) not amenable to curative therapy
- Participant must have a tumor that was previously determined to have exon 19 deletions (Exon 19del) or Exon 21 L858R substitution, as detected by an food and drug administration (FDA)-approved or other validated test in a clinical laboratory improvement amendments (CLIA) certified laboratory (sites in the United states [US]) or an accredited local laboratory (sites outside of the US) in accordance with site standard of care. The biopsy must have been obtained at or after the diagnosis of advanced disease
- Unstained tumor tissue (in a quantity sufficient to allow for central analysis of epidermal growth factor receptor (EGFR) mutation status, see Laboratory Manual) and blood (for circulating tumor deoxyribonucleic acid [ctDNA], digital droplet polymerase chain reaction [ddPCR], and pharmacogenomic analysis), both collected at or after the diagnosis of locally advanced or metastatic NSCLC, must be provided
- Any toxicities from prior anticancer therapy must have resolved to common terminology criteria for adverse events (CTCAE) Grade 1 or baseline level
- Participant must have at least 1 measurable lesion, according to response evaluation criteria in solid tumors (RECIST) v1.1 that has not been previously irradiated. Measurable lesions should not have been biopsied during screening, but if only 1 non-irradiated measurable lesion exists, it may undergo a diagnostic biopsy and be acceptable as a target lesion, provided the baseline tumor assessment scans are performed at least 14 days after the biopsy

Exclusion criteria:

- Participant has received any prior systemic treatment for locally advanced or metastatic disease (adjuvant or neoadjuvant therapy is allowed, if administered more than 12 months prior to the development of locally advanced or metastatic disease)
- Participant has an active or past medical history of leptomeningeal disease
- Participant has spinal cord compression that has not been definitively treated with surgery or radiation or requires steroid treatment within 2 weeks prior to randomization
- Participant has an active or past medical history of interstitial lung disease (ILD)/pneumonitis, including drug-induced or radiation ILD/pneumonitis
- Participant has known allergy, hypersensitivity, or intolerance to the excipients used in formulation of amivantamab, lazertinib, or osimertinib, or any contraindication to the use of osimertinib
- Participant has symptomatic brain metastases. A participant with asymptomatic or previously treated and stable brain metastases may participate in this study