Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Phase 3, Randomized Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib Versus Lazertinib as First-Line Treatment in Patients With EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer.
Protocole ID	MARIPOSA
ClinicalTrials.gov ID	NCT04487080
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Amivantamab en association avec Lazertinib versus Osimertinib versus Lazertinib
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But étude	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)Worldwide, lung cancer is the most commonly diagnosed cancer. In NSCLC the most prevalent actionable driver mutations result in the activation of epidermal growth factor receptor (EGFR). Osimertinib and Lazertinib are EGFR tyrosine kinase inhibitors (TKIs). Amivantamab is a novel bispecific antibody that targets the extracellular domain of both EGFR and MET and can inhibit tumor growth driven by EGFR and mesenchymal-epithelial transition (MET) receptors. Lazertinib inhibits primary activating Exon 19dell and Exon 21 L858R substitution EGFR mutations, and the EGFR T790M+ resistance mutation. The hypothesis is that the amivantamab and lazertinib combination (Arm A) will demonstrate superior PFS compared with single-agent osimertinib (Arm B). The study consists of 3 phases: Screening Phase, Treatment Phase and Follow-up Phase. Participants will undergo response evaluation criteria in solid tumors (RECIST 1.1), pharmacokinetics, and safety evaluations (adverse events, laboratory tests, vital sign measurements, physical examinations).
Critères d'éligibilité	• Participant must have newly diagnosed histologically or cytologically confirmed, locally advanced or metastatic non-small cell lung cancer (NSCLC) that is treatment naive and not amenable to curative therapy including surgical resection or chemoradiation • The tumor harbors 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 • Mandatory submission of unstained tissue from tumor (in a quantity sufficient to allow for central analysis of EGFR mutation status and blood (for circulating tumor deoxyribonucleic acid [ctDNA], digital droplet polymerase chain reaction [ddPCR], and pharmacogenomic analysis) • 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
Critères d'exclusion	• Participant has received any prior systemic treatment for locally advanced or metastatic disease (adjuvant or neoadjuvant therapy for early stage disease 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 with untreated spinal cord compression. A participant that has been definitively treated with surgery or radiation and has a stable neurological status for at least 2 weeks prior to randomization is eligible provided they are off corticosteroid treatment or receiving low-dose corticosteroid treatment less than or equal to (<=) 10 milligrams per day (mg/day) prednisone or equivalent • 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