




Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude de phase III sur le pembrolizumab administré conjointement avec l'association carboplatine/taxane, suivi du pembrolizumab avec ou sans traitement d'entretien par l'olaparib, comme traitement de première intention du cancer du poumon non à petites cellules (CPNPC) squameux métastatique
Protocole ID	MK-7339-008
ClinicalTrials.gov ID	NCT03976362
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Métastatique
Type étude	Clinique
Médicament	Pembrolizumab avec Carboplatine/Taxane (Paclitaxel ou Nab-paclitaxel) suivi de Pembrolizumab avec ou sans Olaparib en maintien
Institution	CISSS DE LA MONTEREGIE-CENTRE  HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	Greenfield Park
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Statut	Fermé
But étude	<p>The current study will compare pembrolizumab (MK-3475) plus maintenance olaparib, vs. pembrolizumab plus maintenance olaparib placebo for the treatment of squamous NSCLC. The study's 2 primary hypotheses are:</p> <ul style="list-style-type: none">• Pembrolizumab plus maintenance olaparib is superior to pembrolizumab plus maintenance olaparib placebo with respect to progression-free survival (PFS) per RECIST 1.1 by blinded independent clinical review (BICR).• Pembrolizumab plus maintenance olaparib is superior to pembrolizumab plus maintenance olaparib placebo with respect to overall survival (OS).
Critères d'éligibilité	<ul style="list-style-type: none">• Have a histologically or cytologically confirmed diagnosis squamous NSCLC.• Have stage IV squamous NSCLC.• Have measurable disease based on RECIST 1.1.• Have not received prior systemic treatment for their advanced/metastatic NSCLC.• Have provided archival tumor tissue sample or newly obtained core or incisional biopsy of a tumor lesion not previously irradiated.• Have a performance status of 0 or 1 on the Eastern Cooperative Oncology Group (ECOG) Performance Status assessed within 7 days prior to the administration of study intervention.• Have a life expectancy of at least 3 months.• Has adequate organ function.• Male and female participants who are not pregnant and of childbearing potential must follow contraceptive guidance during the treatment period and for 180 days afterwards.

Critères d'exclusion

- Has non-squamous histology NSCLC.
- Has a known additional malignancy that is progressing or has progressed within the past 3 years requiring active treatment.
- Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis.
- Has a known hypersensitivity to any components or excipients of carboplatin, paclitaxel or nab-paclitaxel, or olaparib.
- Has a severe hypersensitivity (\geq Grade 3) to pembrolizumab and/or any of its excipients.
- Has an active autoimmune disease that has required systemic treatment in past 2 years.
- Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy.
- Has a known history of human immunodeficiency virus (HIV) infection, a known history of hepatitis B infection, or known active hepatitis C virus infection.
- Has interstitial lung disease, or history of pneumonitis requiring systemic steroids for treatment.
- Has received prior therapy with olaparib or with any other polyadenosine 5' diphosphoribose (polyADP ribose) polymerization (PARP) inhibitor.
- Has received prior therapy with an agent directed to programmed cell death ligand 1 (PD-L1), anti PD-L2, or directed to a stimulatory or co-inhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), OX-40, CD137).
- Has myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML) or with features suggestive of MDS/AML.