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	CIUSSS DE LA MAURICIE-ET-DU-CENTRE-DU-QUEBEC H CHAUR 1991 Boulevard du Carmel, Trois-Rivières, QC, G8Z 3R9
Ville	Trois-Rivières
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Statut	Fermé
But étude	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: • 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	• 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 (≥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.