Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude sur le Pembrolizumab administré en association avec un traitement d'entretien par l'Olaparib ou le Pemetrexed chez des patients atteints de cancer du poumon non à petites cellules (CPNPC) non squameux métastatique
Protocole ID	MK-7339-006
ClinicalTrials.gov ID	NCT03976323
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Médicament	Pembrolizumab avec Pemetrexed/Platine (Carboplatine ou Cisplatine) suivi de Pembrolizumab et Olaparib en maintien vs Pemetrexed en maintien
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
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Statut	Fermé
But étude	The current study will compare pembrolizumab (MK-3475) plus maintenance olaparib, v.s. pembrolizumab plus maintenance pemetrexed for the treatment of nonsquamous NSCLC. The study's 2 primary hypotheses are: 1. Pembrolizumab plus maintenance olaparib is superior to pembrolizumab plus maintenance pemetrexed with respect to progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors (RECIST 1.1) by blinded independent clinical review (BICR) and 2. Pembrolizumab plus maintenance olaparib is superior to pembrolizumab plus maintenance pemetrexed with respect to overall survival (OS).This study has 2 phases: an Induction Phase (4 Cycles) and a Maintenance Phase (Up to 31 cycles of pembrolizumab). In the Induction Phase, participants receive pembrolizumab plus pemetrexed plus platinum (carboplatin or cisplatin). In the Maintenance Phase, participants with a partial or complete disease response or with stable disease after completing four cycles of induction therapy and who meet eligibility criteria will be randomly assigned to receive pembrolizumab plus maintenance olaparib OR pembrolizumab plus maintenance pemetrexed. In the Maintenance Phase, participants receive pembrolizumab for up to 31 cycles plus maintenance olaparib OR maintenance pemetrexed until progressive disease (PD), intolerable toxicities, or physician decision.
Critères d'éligibilité	• Have a histologically or cytologically confirmed diagnosis nonsquamous NSCLC. • Have stage IV nonsquamous NSCLC. • Have confirmation that epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or Proto-oncogene tyrosine-protein kinase (ROS1)-directed therapy is not indicated. • Have measurable disease based on RECIST 1.1. • Have provided archival tumor tissue sample or newly obtained core or incisional biopsy of a tumor lesion not previously irradiated. • Have a life expectancy of at least 3 months. • 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 not received prior systemic treatment for their advanced/metastatic NSCLC. • Have 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 predominantly squamous cell 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 severe hypersensitivity (≥Grade 3) to pembrolizumab and/or any of its excipients. • Has a known hypersensitivity to any components or excipients of cisplatin, carboplatin, pemetrexed, or olaparib. • 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.