Essai Clinique

Généré le 06 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
Institution	CISSS DE LAVAL HOPITAL DE LA CITE-DE-LA-SANTE 1755 boul. René-Laennec, Laval, QC, H7M 3L9
Ville	Laval
Investigateur principal	Dr Nathalie Aucoin
Coordonnateur	Solange Tremblay 450-668-1010 poste 23603
Statut	Fermé
But étude	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 carboplatin plus a taxane (paclitaxel or nab-paclitaxel). 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 olaparib placebo. In the Maintenance Phase, participants randomly assigned to receive pembrolizumab for up to 31 cycles plus maintenance olaparib OR maintenance olaparib placebo until progressive disease (PD), intolerable toxicities, or physician decision."
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. • Note: Adequacy of biopsy specimen for the above analyses must be confirmed by the central laboratory before the participant can receive study intervention(s). Submission of another tumor specimen may be required prior to enrolling the participant, if adequate tumor tissue was not provided the first time. • 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. • Male participants must refrain from donating sperm 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.