Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Randomized, Phase 2 Study of Pembrolizumab And Chemotherapy With or Without MK-4830 as Neoadjuvant Treatment for High-Grade Serous Ovarian Cancer
Protocole ID	MK-4830-002
ClinicalTrials.gov ID	NCT05446870
Type(s) de cancer	Ovaire
Phase	Phase II
Type étude	Clinique
Médicament	Pembrolizumab et chimiothérapie avec ou sans MK-4830
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL
Ville	
Investigateur principal	Dre Lucy Gilbert
Coordonnateur	Phuong-Nam (Nathalie) Nguyen 514-934-1934 poste 31975
Statut	Actif en recrutement
Date d'activation	15-09-2022
But étude	The primary objective is to evaluate in participants with high-grade serous ovarian cancer (HGSOC), whether the reduction from baseline in circulating tumor DNA (ctDNA) at Cycle 3 (ΔctDNA) is larger in participants receiving MK-4830 + pembrolizumab in combination with standard of care (SOC) therapy than in those receiving pembrolizumab + SOC therapy.
Critères d'éligibilité	• Has histologically-confirmed International Federation of Gynecology and Obstetrics (FIGO) Stage III or Stage IV HGSOC, primary peritoneal cancer, or fallopian tube cancer. • Is a candidate for carboplatin and paclitaxel chemotherapy, to be administered in the neoadjuvant and adjuvant setting. • Is a candidate for interval debulking surgery. • Is able to provide archival tissue or newly obtained core, incisional, or excisional biopsy of a tumor lesion. • Has adequate organ functions.
Critères d'exclusion	• Has a non-HGSOC histology. • Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. • Has a known additional malignancy that is progressing or has required active treatment within the past 3 years. • Has received prior treatment for any stage of OC, including radiation or systemic anticancer therapy. • Planned or has been administered intraperitoneal chemotherapy as first-line therapy. • Has received prior therapy with an anti-programmed cell death 1 protein (PD-1), anti-programmed cell death 1 ligand 1 (PD-L1), anti-programmed cell death 1 ligand 2 (PD-L2), anti-immunoglobulin-like transcript 4 (ILT4), or anti-human leukocyte antigen (HLA)-G agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor. • Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. • Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks before the first dose of study intervention.

- Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior the first dose of study medication.
- Has known active Central Nervous System (CNS) metastases and/or carcinomatous meningitis.
- Has severe hypersensitivity to pembrolizumab, carboplatin, paclitaxel (or docetaxel, if applicable), Avastin or biosimilar (if using) and/or any of their excipients.
- Has an active autoimmune disease that has required systemic treatment in past 2 years.
- Has an active infection requiring systemic therapy.
- Has a known history of human immunodeficiency virus (HIV) infection.
- Has a known history of hepatitis B or known active hepatitis C virus infection.
- Has received colony-stimulating factors within 4 weeks prior to receiving study intervention on Day 1 of Cycle 1.
- Has had surgery <6 months prior to Screening to treat borderline ovarian tumors, early-stage OC, or early-stage fallopian tube cancer.
- Has a known psychiatric or substance abuse disorder that would interfere with the participant's ability to cooperate with the requirements of the study.
- Has current, clinically relevant bowel obstruction.
- Has a history of hemorrhage, hemoptysis, or active gastrointestinal (GI) bleeding within 6 months prior to randomization.
- Has uncontrolled hypertension.
- Has had an allogenic tissue/solid organ transplant.
- .Has either had major surgery within 3 weeks of randomization or has not recovered from any effects of any major surgery.