Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Clinical Trial of Pembrolizumab (MK-3475) Evaluating Predictive Biomarkers in Subjects With Advanced Solid Tumors
Protocole ID	MK-3475-158/KEYNOTE-158
ClinicalTrials.gov ID	NCT02628067
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dr Wilson Miller
Coordonnateur	Gayathri Kuruba 514-340-8222 poste 26187
Statut	Fermé
Date d'activation	15-01-2016
But étude	In this study, participants with multiple types of advanced (unresectable and/or metastatic) solid tumors that have progressed on standard of care therapy will be treated with pembrolizumab.
Critères d'éligibilité	• Histologically or cytologically-documented, advanced solid tumor of one of the following types: • Anal Carcinoma • Biliary Adenocarcinoma (gallbladder or biliary tree (intrahepatic or extrahepatic cholangiocarcinoma) except Ampulla of Vater cancers) • Neuroendocrine Tumors (well- and moderately-differentiated) of the lung, appendix, small intestine, colon, rectum, or pancreas • Endometrial Carcinoma (sarcomas and mesenchymal tumors are excluded) • Cervical Carcinoma • Vulvar Carcinoma • Small Cell Lung Carcinoma • Mesothelioma • Thyroid Carcinoma • Salivary Gland Carcinoma (sarcomas and mesenchymal tumors are excluded) • OR • Any other advanced solid tumor, with the exception of colorectal carcinoma (CRC), which is Microsatellite Instability (MSI)-High (MSI-H) • Progression of tumor or intolerance to therapies known to provide clinical benefit. There is no limit to the number of prior treatment regimens • Can supply tumor tissue for study analyses (dependent on tumor type) • Radiologically-measurable disease • Performance status of 0 or 1 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale • Adequate organ function • Female participants of childbearing potential must be willing to use adequate contraception for the course of the study through 120 days after the last dose of study medication • Male participants with partners of must childbearing potential must be willing to use adequate

	contraception for the course of the study through 120 days after the last dose of study medication
Critères d'exclusion	• Currently participating and receiving study therapy or has participated in a study of an investigational agent and received study therapy or used an investigational device within 4 weeks of the first dose of study medication • Diagnosis of immunodeficiency or receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication • Active autoimmune disease that has required systemic treatment in the past 2 years • Prior anti-cancer monoclonal antibody (mAb) within 4 weeks prior to study Day 1 or not recovered from an adverse event caused by mAbs administered more than 4 weeks earlier • Prior chemotherapy, targeted small molecule therapy, or radiation therapy within 2 weeks of study Day 1 or not recovered from adverse events caused by a previously administered agent • Known additional malignancy within 2 years prior to enrollment with the exception of curatively treated basal cell carcinoma of the skin, squamous cell carcinoma of the skin and/or curatively resected in situ cervical and/or in situ breast cancers • Known active central nervous system (CNS) metastases and/or carcinomatous meningitis • Evidence of active non-infectious pneumonitis • Active infection requiring systemic therapy • Known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the study • Pregnant, breastfeeding, or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of study medication • Previously participated in any other pembrolizumab (MK-3475) study, or received prior therapy with an anti-programmed cell death (PD)-1, anti-PD-Ligand 1 (L1), anti-PD-L2, or any other immunomodulating mAb or drug specifically targeting T-cell co-stimulation or checkpoint pathways • Known history of Human Immunodeficiency Virus (HIV) • Known active Hepatitis B or C • Received live vaccine within 30 days of planned start of study medication