Essai Clinique

Généré le 18 avr. 2024 à partir de

Titre	Étude de phase 3, comparant l'association pembrolizumab (MK-3475) et chimiothérapie à l'association placebo et chimiothérapie chez des patients atteints d'un adénocarcinome de l'estomac ou de la jonction gastro-œsophagienne
Protocole ID	KEYNOTE-585
ClinicalTrials.gov ID	NCT03221426
Type(s) de cancer	Estomac
Phase	Phase III
Stade	Adénocarcinomes
Type étude	Traitement
Médicament	Pembrolizumab et chimiothérapie
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
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But étude	The purpose of this study is to evaluate the efficacy of pembrolizumab (MK-3745) in the neoadjuvant (prior to surgery) or adjuvant (after surgery) treatment of previously untreated adults with gastric and gastroesophageal junction (GEJ) adenocarcinoma.
Critères d'éligibilité	• Has previously untreated localized gastric or GEJ adenocarcinoma as defined by T3 or greater primary lesion or the presence of any positive nodes - N+ (clinical nodes) without evidence of metastatic disease. • Plans to proceed to surgery following pre-operative chemotherapy based on standard staging studies per local practice. • Is willing to provide tissue from a tumor lesion at baseline and at time of surgery. • Has an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 1 within 3 days prior to the first dose of study treatment. • Has adequate organ function. • All participants of childbearing potential must be willing to use an adequate method of contraception for the course of the study through 120 days after the last dose of pembrolizumab, capecitabine, or 5FU; or through 6 months following the last dose of cisplatin, whichever is greater. • Has life expectancy of greater than 6 months.
Critères d'exclusion	• Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis. • Has an active infection requiring systemic therapy. • Is currently participating in or has participated in a trial of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment. • Has received prior therapy with an anti-programmed cell death protein-1 (anti-PD-1), anti-programmed cell death-ligand 1 (anti-PD-L1), or anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (i.e., cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], tumor necrosis factor receptor superfamily member 4 [OX-40], necrosis

factor receptor superfamily member 9 [CD137]) or has previously participated in a Merck pembrolizumab (MK-3475) clinical trial.
- Has received prior systemic anti-cancer therapy including investigational agents for the current malignancy.
- Has received prior radiotherapy within 2 weeks of start of study treatment for any other condition.
- 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 14 days prior the first dose of study treatment.
- Has a known additional malignancy that is progressing or has required active treatment within the past 5 years. Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ that have undergone potentially curative therapy are not excluded.
- Has a known severe hypersensitivity (≥ Grade 3) to pembrolizumab, its active substance and/or any of its excipients, or to any of the study chemotherapy agents and/or to any of their excipients.
- Has an active autoimmune disease that has required systemic treatment in past 2 years.
- 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 a known history of active tuberculosis (TB).
- Is pregnant or 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 treatment.
- Has received a live vaccine within 30 days prior to the first dose of study treatment.