Essai Clinique

Généré le 06 mai 2024 à partir de

Titre	Étude de phase III à répartition aléatoire visant à évaluer l'efficacité et l'innocuité de l'association lenvatinib et pembrolizumab avec une chimiothérapie par rapport au traitement standard comme intervention de première intention chez les participants atteints d'un adénocarcinome gastro-œsophagien avancé/métastatique
Protocole ID	MK-7902-015 (LEAP-015)
ClinicalTrials.gov ID	NCT04662710
Type(s) de cancer	Estomac
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Lenvatinib + pembrolizumab + chimiothérapie versus traitement standard de chimiothérapie
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE H HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
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Statut	Fermé
But étude	The purpose of this study is to assess the efficacy and safety of lenvatinib (E7080/MK-7902) plus pembrolizumab (MK-3475) plus chemotherapy compared with chemotherapy alone in participants with advanced/metastatic gastroesophageal cancerThe primary study hypotheses are that lenvatinib plus pembrolizumab plus chemotherapy is superior to chemotherapy alone for both overall survival (OS) and progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1) as assessed by blinded independent central review (BICR), in participants with programmed cell death-ligand 1 (PD-L1) Combined Positive Score (CPS) ≥1 and in all participants.
Critères d'éligibilité	• Has histologically and/or cytologically confirmed diagnosis of previously untreated, locally advanced unresectable or metastatic gastroesophageal adenocarcinoma • Is not expected to require tumor resection during the treatment course • Has gastroesophageal adenocarcinoma that is not HER-2/neu positive • Has measurable disease as defined by RECIST 1.1 by scan with IV contrast as determined by the local site investigator • Male participants agree to refrain from donating sperm and agree to either remain abstinent from heterosexual intercourse as their preferred and usual lifestyle OR agree to use contraception, during the intervention period and for ≥7 days after last dose of lenvatinib or 90 days after last dose of chemotherapy-whichever comes last • Female participants not pregnant or breastfeeding are eligible to participate if not a women of childbearing potential (WOCBP), or if a WOCBP they either use a contraceptive method that is highly effective OR remain abstinent from heterosexual intercourse as their preferred and usual lifestyle, and do not donate eggs (ova, oocytes) to others or freeze/store for their own use, during the intervention period through 120 days after last dose of pembrolizumab, 30 days after last dose of lenvatinib, or 180 days after last dose of chemotherapy-whichever occurs last • Has a performance status of 0 or 1 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale within 3 days prior to the first dose of study treatment • Has adequately controlled blood pressure with or without antihypertensive medications

	• Has adequate organ function
Critères d'exclusion	• Has had previous therapy for locally advanced unresectable or metastatic gastric/gastroesophageal junction (GEJ) esophageal adenocarcinoma • Has had major surgery within 28 days prior to first dose of study interventions • Has had radiotherapy within 14 days of randomization • Has a known additional malignancy that is progressing or has required active treatment within the past 5 years • Has known CNS metastases and/or carcinomatous meningitis • Has severe hypersensitivity (≥Grade 3) to treatment with an monoclonal antibody (mAb) or known sensitivity or intolerance to any component of lenvatinib, pembrolizumab, study chemotherapy agents and/or to any excipients, murine proteins, or platinum containing products • Has had an allogeneic tissue/solid organ transplant • Has perforation risks or significant gastrointestinal (GI) bleeding • Has GI obstruction, poor oral intake (CAPOX participants), or difficulty in taking oral medication (CAPOX participants) • Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor • Has received prior therapy with anti- vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor or anti-VEGF mAb • Has received a live or live-attenuated vaccine within 30 days before the first dose of study drug • Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs) • Has radiographic evidence of encasement or invasion of a major blood vessel, or of intratumoral cavitation • Has inadequate cardiac function • Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease • Has poorly controlled diarrhea • Has accumulation of pleural, ascitic, or pericardial fluid requiring drainage or diuretic drugs within 2 weeks prior to enrollment. • Has peripheral neuropathy ≥Grade 2 • Has a known history of human immunodeficiency virus (HIV) or HIV 1/2 antibodies • Has a known history of hepatitis B (defined as HBsAg reactive) or known active hepatitis C virus (defined as HCV RNA [qualitative] is detected) infection • Has weight loss of >20% within the last 3 months