Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	Étude de phase III à double insu et à deux groupes de traitement visant à évaluer l'innocuité et l'efficacité du pembrolizumab par rapport au placebo comme traitement adjuvant chez des participants atteints d'un carcinome hépatocellulaire et ayant présenté une réponse radiologique complète après résection chirurgicale ou ablation locale
Protocole ID	MK-3475-937
ClinicalTrials.gov ID	NCT03867084
Type(s) de cancer	Foie
Phase	Phase III
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
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Statut	Fermé
But étude	This study will evaluate the safety and efficacy of pembrolizumab (MK-3475) versus placebo as adjuvant therapy in participants with hepatocellular carcinoma (HCC) and complete radiological response after surgical resection or local ablation. The primary hypotheses of this study are that adjuvant pembrolizumab is superior to placebo with respect to: 1) recurrence-free survival (RFS) as assessed by blinded independent central review (BICR); and 2) overall survival (OS).
Critères d'éligibilité	• Has a diagnosis of HCC by radiological criteria and/or pathological confirmation. • Has an eligibility scan (CT of the chest, triphasic CT scan or MRI of the abdomen, and CT or MRI of the pelvis) confirming complete radiological response ≥4 weeks after complete surgical resection or local ablation. Randomization needs to occur within 12 weeks of the date of surgical resection or local ablation. • Has no radiologic evidence of disease prior to enrollment. • Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 within 7 days prior to Cycle 1, Day 1. • Has a Child-Pugh class A liver score (5 to 6 points) within 7 days prior to Cycle 1, Day 1. • Has alpha fetoprotein (AFP) concentration lower than 400 ng/mL within 28 days prior to Cycle 1, Day 1. • Has controlled hepatitis B (Hep B). • Has recovered adequately from toxicity and/or complications from the local intervention (surgical resection or local ablation) prior to starting study treatment. • If female, is not pregnant or breastfeeding, and at least one of the following conditions applies: 1) Is not a woman of childbearing potential (WOCBP); or 2) Is a WOCBP and using a contraceptive method that is highly effective or be abstinent from heterosexual intercourse as their preferred and usual lifestyle (a WOCBP must have a negative pregnancy test within 72 hours before the first dose of study treatment). • If undergoing surgical resection, has submitted a tumor tissue sample during Screening. • Has adequate organ function.

Critères d'exclusion	• Has a known additional malignancy that is progressing or has required active antineoplastic treatment (including hormonal) or surgery within the past 3 years. • Has had esophageal or gastric variceal bleeding within the last 6 months. • Has clinically apparent ascites on physical examination. • Has had clinically diagnosed hepatic encephalopathy in the last 6 months. • Has received local therapy to liver ablation other than with radiofrequency or microwave ablation. • Has a history of (noninfectious) pneumonitis that required steroids or has current pneumonitis. • Has an active infection requiring systemic therapy. • Has dual active Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) infection at study entry. • Has a known history of human immunodeficiency virus (HIV) infection. • Has known active tuberculosis (TB; Bacillus tuberculosis). • 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 co-inhibitory T-cell receptor (eg, CTLA-4, OX-40, CD137). • Has received prior systemic anti-cancer therapy for HCC including investigational agents. • Is receiving any of the following prohibited concomitant therapies:1) Antineoplastic systemic chemotherapy or biological therapy; 2) Immunotherapy not specified in this protocol; 3) Investigational agents other than pembrolizumab; 4) Radiation therapy; 5) Oncological surgical therapy; or systemic glucocorticoids for any purpose other than to modulate symptoms from an AE that is suspected to have an immunologic etiology. • Has received a live vaccine within 30 days prior to the first dose of study treatment. • Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to Cycle 1, Day 1. • Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to Cycle 1, Day 1. • Has 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 known psychiatric or substance abuse disorder that would interfere with the participant's ability to cooperate with the requirements of the study. • 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 had an allogenic tissue/solid organ transplant.