Essai Clinique

Généré le 14 mai 2024 à partir de

Titre	Essai de prolongation de phase III, multicentrique et ouvert, visant à évaluer l'innocuité et l'efficacité à long terme du traitement par le pembrolizumab chez des participants atteints de tumeurs à un stade avancé actuellement traités ou suivis dans un essai portant sur le pembrolizumab
Protocole ID	MK-3475-587
ClinicalTrials.gov ID	NCT03486873
Type(s) de cancer	Tumeurs solides
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Yves Fradet
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Statut	Actif en recrutement
But étude	The purpose of this study is to evaluate the long-term safety and efficacy of pembrolizumab (MK-3475) in participants from previous Merck pembrolizumab-based parent studies who roll-over into this extension study. This study will consist of three phases: 1) First Course Phase, 2) Survival Follow-up Phase or 3) Second Course Phase. Each participant will roll-over to this extension study in one of the following three phases, depending on the study phase they were in at the completion of the parent study. Participants who were in the First Course Phase of study treatment in their parent study will enter the First Course Phase of this study and complete up to 35 cycles of study treatment with pembrolizumab or a pembrolizumab-based combination. Participants who were in the Follow-up Phase in the parent study (post-treatment or Survival Follow-up Phase) will enter the Survival Follow-up Phase of this study. Participants who were in the Second Course Phase in their parent study will enter Second Course Phase of this study and complete up to 17 cycles of study treatment with pembrolizumab or a pembrolizumab-based combination. Any participant originating from a parent trial where crossover to pembrolizumab was permitted upon disease progression may be eligible for 35 doses (approximately 2 years) of pembrolizumab, if they progress while on the control arm and pembrolizumab is approved for the indication in the country where the potential eligible crossover participant is being evaluated.
Critères d'éligibilité	• Advanced unresectable or metastatic tumor(s) • Currently enrolled in a Merck-sponsored pembrolizumab study and is receiving study treatment or in a Follow-up Phase at the time MK-3475-587 is open. The parent studies must have completed all regulatory requirements and submissions, if any, or have fully addressed their primary endpoint(s) before all their participants roll over into this MK-3475-587 extension study. Additional eligibility criteria for participants who enter Second Course Phase once they are enrolled on MK-3475-587: • Has not received any anticancer systemic treatment since the last dose of pembrolizumab or a pembrolizumab-based combination in First Course Phase • Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Demonstrates adequate organ function

	• Have resolution of any toxic effect(s) of First Course Phase trial treatment with pembrolizumab or a pembrolizumab-based combination to Grade 1 or less (except alopecia) before trial treatment in Second Course Phase is started. If participant received major surgery or radiation therapy of >30 Gray (Gy), they must have recovered from the toxicity and/or complications of the intervention. • Male participant must agree to use contraception during the Second Course Phase study treatment period and for ≥120 days, corresponding to time needed to eliminate any study combination treatment(s), plus 75 days (a spermatogenesis cycle) for study treatments with evidence of genotoxicity at any dose after the last dose of study treatment and refrain from donating sperm during this period. • A female participant is eligible to enroll if she is not pregnant, not breastfeeding, and ≥1 of the following conditions applies: A woman of childbearing potential (WOCBP) who agrees to use contraception during the study treatment period and for ≥120 days (corresponding to time needed to eliminate any study combination treatment(s) plus 30 days (a menstruation cycle) for study treatments with risk of genotoxicity.
Critères d'exclusion	There are no exclusion criteria to participate in MK-3475-587. Participants are excluded from entering Second Course trial treatment once they are enrolled on MK-3475-587 if any of the following criteria applies: • Has severe hypersensitivity (≥ Grade 3) to pembrolizumab and/or any of its excipients • Has received a live vaccine within 30 days prior to the first dose of Second Course Phase trial treatment • 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 to the Cycle 1 Day 1 of Second Course Phase • Has a known additional malignancy that is progressing or requires active treatment. Exceptions include early stage cancers (carcinoma in situ or Stage 1) treated with curative intent, melanoma (non-ulcerated, thin primary), basal cell carcinoma of the skin, squamous cell carcinoma of the skin, in situ cervical cancer, or in situ breast cancer that has undergone potentially curative therapy. • Has known active central nervous system metastases and/or carcinomatous meningitis • Has an active autoimmune disease that has required systemic treatment in the past 2 years (i.e., use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g. thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed. • Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis. Note: Participants that experienced pneumonitis during First Course that did not meet the criteria for permanent discontinuation are eligible. • NSCLC participants only: Has interstitial lung disease • Has an active infection requiring systemic therapy • Has a known history of human immunodeficiency virus (HIV) infection. • Has a known history of or is positive for hepatitis B or hepatitis C • Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the study, starting with the Second Course Phase eligibility Visit through 120 days after the last dose of study treatment. • Has severe cardiovascular disease, i.e., arrhythmias, requiring chronic treatment, congestive heart failure (New York Heart Association Class III or IV) or symptomatic ischemic heart disease. • Has hepatic decompensation (Child-Pugh score >6 [class B and C]) • Has uncontrolled thyroid dysfunction • Has uncontrolled diabetes mellitus • Has had an allogeneic tissue/solid organ transplant • Has a known history of active tuberculosis (TB; Bacillus tuberculosis)