Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	A Phase 1/1b Open-label, Multicenter Clinical Study of MK-0472 as Monotherapy and Combination Therapy in Participants With Advanced/Metastatic Solid Tumors.
Protocole ID	MK-0472-001
ClinicalTrials.gov ID	NCT05853367
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	MK-0472 en monothérapie et en association avec pembrolizumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Rahima Jamal
Coordonnateur	Adeline Hamon 514-890-8000 poste 30737
Statut	Actif en recrutement
Date d'activation	27-09-2023
But étude	The purpose of this study is to assess the efficacy, safety, and tolerability of MK-0472 administered as monotherapy and in combination with pembrolizumab (MK-3475) in participants with histologically or cytologically confirmed diagnosis of advanced/metastatic solid tumors. There is no primary hypothesis to be tested for this study.
Critères d'éligibilité	The main inclusion criteria include but are not limited to the following: • Histologically or cytologically confirmed advanced/metastatic solid tumor by pathology report with oncogenic receptor tyrosine kinase (RTK) pathway alterations confirmed by a historical report or local testing and have received, or been intolerant to, all available treatment known to confer clinical benefit • Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received HBV antiviral therapy for at least 4 weeks, and have undetectable HBV viral load prior to randomization • Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening • Participants with human immunodeficiency virus (HIV) infection must have well controlled HIV on stable (>4 weeks) antiretroviral therapy (ART)
Critères d'exclusion	The main exclusion criteria include but are not limited to the following: • Has not recovered to common terminology criteria for adverse events (CTCAE) Grade 1 or better from any adverse events that were due to cancer therapeutics administered more than 4 weeks earlier. Participants receiving ongoing replacement hormone therapy for endocrine immune-related AEs will not be excluded from participation in this study • Has history of a second malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years • History of hyperparathyroidism or hypercalcemia • Has one or more of the following ophthalmological findings/conditions: a) Intraocular pressure >21 mm Hg and/or any diagnosis of glaucoma b) Diagnosis of central serous retinopathy, retinal

vein occlusion, or retinal artery occlusion and c) Diagnosis of retinal degenerative disease
- Has clinically significant cardiovascular disease
- Bullous exfoliative skin disorders of any grade
- Known hypersensitivity to MK-0472 or pembrolizumab, or any of their excipients
- Received therapy with a proton-pump inhibitor or an H2 histamine blocker receptor antagonist within 7 days before the first scheduled day of study dosing
- Has discontinued prior therapy with an anti-programmed cell death-1 (PD-1), anti-programmed death-ligand 1 (PD-L1), or anti-programmed death-ligand 2 (PD-L2) agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor due to an adverse event
- Received prior systemic anticancer therapy including investigational agents within 4 weeks before first dose
- Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention
- Has received an investigational agent or has used an investigational device within 4 weeks prior to study intervention administration
- Has diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication
- Has known additional malignancy that is progressing or has required active treatment within the past 2 years
- Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis. Participants with previously treated brain metastases may participate provided they are radiologically stable for at least 4 weeks as confirmed by repeat imaging performed during the study screening, are clinically stable and have not required steroid treatment for at least 14 days before the first dose of study intervention
- Has active autoimmune disease that has required systemic treatment in the past 2 years except replacement therapy
- Has history of pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
- Has active infection requiring systemic therapy
- Has history of allogeneic tissue/solid organ transplant
- Have not adequately recovered from major surgery or have ongoing surgical complications