Essai Clinique

Généré le 13 mai 2025 à partir de

Titre	A Phase 1b/2 Study of Immune and Targeted Combination Therapies in Participants With RCC (U03): Substudy 03B
Protocole ID	MK-3475-03B
ClinicalTrials.gov ID	NCT04626518
Type(s) de cancer	Rein
Phase	Phase I-II
Type étude	Clinique
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	
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Statut	Fermé
But étude	Substudy 03B is part of a larger research study that is testing experimental treatments for renal cell carcinoma (RCC). The larger study is the umbrella study (U03). The goal of substudy 03B is to evaluate the safety and efficacy of experimental combinations of investigational agents in participants with advanced second line plus (2L+) clear cell renal cell carcinoma (ccRCC). This substudy will have two phases: a safety lead-in phase and an efficacy phase. The safety lead-in phase will be used to demonstrate a tolerable safety profile for the combination of investigational agents. There will be no hypothesis testing in this study.
Critères d'éligibilité	• Has a histologically confirmed diagnosis of locally advanced/metastatic ccRCC • Has experienced disease progression on or after having received systemic treatment for locally advanced or metastatic RCC with a PD-(L)1 checkpoint inhibitor (in sequence or in combination with a vascular endothelial growth factor - tyrosine kinase inhibitor [VEGF-TKI]) where PD-(L)1 checkpoint inhibitor treatment progression is defined by meeting ALL of the following criteria: (a) has received ≥2 doses of an anti-PD-(L)1 monoclonal antibody (mAb) (b) has shown radiographic disease progression during or after an anti-PD-(L)1 mAb as defined by RECIST 1.1 by investigator (c) disease progression has been documented within 12 weeks from the last dose of an anti-PD-(L)1 mAb • Has experienced disease progression on or after having received systemic treatment for locally advanced or metastatic RCC with a VEGF-TKI (in sequence or in combination with a PD-[L]1 checkpoint inhibitor) where VEGF-TKI treatment progression is defined by meeting the following criterion: has shown radiographic disease progression during or after a treatment with a VEGF-TKI as defined by RECIST 1.1 by investigator • Is able to swallow oral medication • Has adequate organ function • Participants receiving bone resorptive therapy must have therapy initiated at least 2 weeks before randomization/allocation • Has resolution of toxic effects of the most recent prior therapy to ≤Grade 1 • If participants receive major surgery or radiation therapy, they must have recovered from complications from the intervention • Has adequately controlled blood pressure (BP ≤150/90 mm Hg) with no change in hypertensive medications within 1 week before randomization/allocation • Male participants are abstinent from heterosexual intercourse or agree to use contraception during treatment with and for at least 7 days after the last dose of lenvatinib and /or belzutifan; 7 days after lenvatinib and/or belzutifan is stopped, if the participant is only receiving pembrolizumab, pembrolizumab/quavonlimab, MK-4280A, MK-4830 or a combination of the

	aforementioned drugs, no contraception is needed • Female participant is not pregnant or breastfeeding and is not a woman of childbearing potential (WOCBP) or is a WOCBP abstinent from heterosexual intercourse or using contraception during the intervention period and for at least 120 days after the last dose of pembrolizumab, pembrolizumab/quavonlimab, MK-4280A, MK-4830 or 30 days after the last dose of lenvatinib or belzutifan, whichever occurs last
Critères d'exclusion	• Has urine protein ≥1 g/24 hours and has any of the following: (a) hypoxia defined as a pulse oximeter reading <92% at rest, or (b) requires intermittent supplemental oxygen, or (c) requires chronic supplemental oxygen • Has clinically significant cardiovascular disease within 12 months from the first dose of study intervention administration • Has had major surgery within 3 weeks before first dose of study interventions • Has a history of lung disease • Has a history of inflammatory bowel disease • Has preexisting gastrointestinal (GI) or non-GI fistula • Has malabsorption due to prior GI surgery or disease • Has previously received treatment with a combination of pembrolizumab plus lenvatinib • Has received prior treatment with belzutifan • Has received prior radiotherapy within 2 weeks of start of study intervention • Has received a live or live attenuated vaccine within 30 days before the first dose of study intervention; killed vaccines are allowed • Has received more than 4 previous systemic anticancer treatment regimens • Has a diagnosis of immunodeficiency or is receiving any form of immunosuppressive therapy within 7 days prior to the first dose of study intervention • Has known additional malignancy that is progressing or has required active treatment within the past 3 years • Has known central nervous system (CNS) metastases and/or carcinomatous meningitis • Has an active autoimmune disease that has required systemic treatment in the past 2 years; replacement therapy is not considered a form of systemic treatment and is allowed • Has an active infection requiring systemic therapy • Has a known history of human immunodeficiency virus (HIV) infection • Has a known history of Hepatitis B • Has had an allogenic tissue/solid organ transplant