



Essai Clinique

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Titre	A Phase 1b/2 Study of Immune and Targeted Combination Therapies in Participants With RCC (U03): Substudy 03A
Protocole ID	MK-3475-03A
ClinicalTrials.gov ID	NCT04626479
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	Actif en recrutement
But étude	Substudy 03A 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 03A is to evaluate the safety and efficacy of experimental combinations of investigational agents in participants with advanced first line (1L) 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	<ul style="list-style-type: none">• Has a histologically confirmed diagnosis of locally advanced/metastatic ccRCC• Has received no prior systemic therapy for advanced RCC; prior neoadjuvant/adjuvant therapy for RCC is acceptable if completed ≥ 12 months before randomization/allocation• 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 \leq 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 $\leq 150/90$ 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 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 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 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 drug; 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