Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination With Lenvatinib (MK-7902) vs Cabozantinib in Participants With Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy
Protocole ID	MK-6482-011
ClinicalTrials.gov ID	NCT04586231
Type(s) de cancer	Rein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	belzutifan en association avec le lenvatinib versus cabozantinib
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	
Investigateur principal	Dre Catherine Sperlich
Coordonnateur	Valérie Painchaud-Lachapelle 450-466-5000 poste 2278
Statut	Fermé
But étude	This study will compare the efficacy and safety of belzutifan + lenvatinib versus cabozantinib in participants with advanced renal cell carcinoma (RCC) with clear cell component after prior therapy.The primary hypothesis is that belzutifan + lenvatinib is superior to cabozantinib in terms of progression-free survival or overall survival.
Critères d'éligibilité	• Unresectable, locally advanced or metastatic clear cell renal cell carcinoma (RCC). • Disease progression on or after an anti-programmed cell death-1/ligand 1 (PD-1/L1) therapy as either first or second-line treatment for locally advanced/metastatic RCC or as adjuvant treatment with progression on or within 6 months of last dose. • Measurable disease per RECIST 1.1 criteria as assessed by local study investigator. • Karnofsky performance status (KPS) score of at least 70% assessed within 10 days before randomization. • Received no more than 2 prior systemic regimens. • Received only 1 prior antiPD-1/L1 therapy for adjuvant or locally advanced/metastatic RCC. • A male participant is eligible to participate if he is abstinent from heterosexual intercourse or agrees to use contraception during the intervention period and for at least 7 days after the last dose of belzutifan or lenvatinib in the belzutifan+lenvatinib arm, whichever occurs last, and 23 days after the last dose of cabozantinib. • A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least 1 of the following conditions applies: Not a woman of childbearing potential (WOCBP) or a WOCBP who agrees to follow the contraceptive guidance during the intervention period and for at least 30 days after the last dose of study intervention in the belzutifan+ lenvatinib arm, or 120 days after the last dose of study intervention in the cabozantinib arm. • Adequately controlled blood pressure. • Adequate organ function.

Critères d'exclusion	• A pulse oximeter reading <92% at rest, requires intermittent supplemental oxygen, or requires chronic supplemental oxygen. • Known additional malignancy that is progressing or has required active treatment within the past 3 years except for basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (eg, breast carcinoma, cervical cancer in situ) that have undergone potentially curative therapy. • Known central nervous system (CNS) metastases and/or carcinomatous meningitis. • Clinically significant cardiac disease within 6 months of first dose of study intervention. • Prolongation of QTc interval to >480 ms. • Symptomatic pleural effusion (e.g.,cough, dyspnea, pleuritic chest pain) that is not clinically stable. • Pre-existing ≥Grade 3 gastrointestinal or nongastrointestinal fistula. • Moderate to severe hepatic impairment. • History of significant bleeding within 3 months before randomization. • History of solid organ transplantation. • Known psychiatric or substance abuse disorder that would interfere with cooperation with the requirements of the study. • Unable to swallow orally administered medication or has a gastrointestinal disorder affecting absorption (e.g., gastrectomy, partial bowel obstruction, malabsorption). • Known hypersensitivity or allergy to the active pharmaceutical ingredients or any component of the study intervention formulations. • Received colony-stimulating factors [eg, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GMCSF) or recombinant erythropoietin (EPO)] within 28 days before randomization. • Prior treatment with belzutifan or another hypoxia-inducible factor (HIF)-2α inhibitor. • Prior treatment with lenvatinib. • Prior treatment with cabozantinib. • Currently participating in a study of an investigational agent or using an investigational device. • Active infection requiring systemic therapy. • History of human immunodeficiency virus (HIV) infection. • History of hepatitis B or known active hepatitis C infection.