Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	An Open-label, Randomized Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in Combination With Belzutifan (MK-6482) and Lenvatinib (MK-7902), or MK-1308A in Combination With Lenvatinib, Versus Pembrolizumab and Lenvatinib, as First-Line Treatment in Participants With Advanced Clear Cell Renal Cell Carcinoma (ccRCC)
Protocole ID	MK-6482-012
ClinicalTrials.gov ID	NCT04736706
Type(s) de cancer	Rein
Phase	Phase III
Type étude	Clinique
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
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Statut	Actif en recrutement
But étude	The goal of this study is to evaluate the efficacy and safety of pembrolizumab plus belzutifan plus lenvatinib or pembrolizumab/quavonlimab plus lenvatinib versus pembrolizumab plus lenvatinib as first-line treatment in participants with advanced clear cell renal cell carcinoma (ccRCC).The primary hypotheses are (1) pembrolizumab plus belzutifan plus lenvatinib is superior to pembrolizumab plus lenvatinib with respect to progression-free survival (PFS) and overall survival (OS), in advanced ccRCC participants and (2) pembrolizumab/quavonlimab plus lenvatinib is superior to pembrolizumab plus lenvatinib with respect to PFS and OS, in advanced ccRCC participants.
Critères d'éligibilité	• Has histologically confirmed diagnosis of RCC with clear cell component • Has received no prior systemic therapy for advanced ccRCC • Male participants are abstinent from heterosexual intercourse or agree to use contraception during and for at least 7 days after last dose of study intervention with belzutifan and lenvatinib • Female participants are not pregnant or breastfeeding and are either not a woman of child-bearing potential (WOCBP) or use a contraceptive method that is highly effective or are abstinent from heterosexual intercourse during the intervention period and for at least 120 days after pembrolizumab or pembrolizumab/quavonlimab or for at least 30 days after last dose of lenvatinib or belzutifan, whichever occurs last • Has adequately controlled blood pressure with or without antihypertensive medications • Has adequate organ function • Participants receiving bone resorptive therapy must have therapy initiated at least 2 weeks prior to randomization/allocation
Critères d'exclusion	• Has a known additional malignancy that is progressing or has required active treatment within the past 3 years • Has had major surgery, other than nephrectomy within 4 weeks prior to randomization • Has known central nervous system (CNS) metastases and/or carcinomatous meningitis • Has received prior radiotherapy within 2 weeks prior to first dose of study intervention • Has hypoxia or requires intermittent supplemental oxygen or requires chronic supplemental oxygen • Has clinically significant cardiac disease within 12 months from first dose of study intervention • Has a history of interstitial lung disease • Has symptomatic pleural effusion; a participant who is clinically stable following treatment of

this condition is eligible
- Has preexisting gastrointestinal or non-gastrointestinal fistula
- Has a 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 treatment
- Has a known psychiatric or substance abuse disorder that would interfere with requirements of the study
- Has received a live or live-attenuated vaccine within 30 days before the first dose of study drug; killed vaccines are allowed
- Has an active autoimmune disease that has required systemic treatment in the past 2 years
- Has a history of noninfectious pneumonitis that required steroids or has current pneumonitis
- 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 radiographic evidence of intratumoral cavitation, encasement or invasion of a major blood vessel
- Has clinically significant history of bleeding within 3 months prior to randomization
- Has had an allogenic tissue/solid organ transplant