Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Étude de phase III, à répartition aléatoire, multicentrique et à double insu visant à comparer l'efficacité et l'innocuité du belzutifan en association avec le pembrolizumab à celles d'un placebo en association avec le pembrolizumab dans le traitement adjuvant d'un hypernéphrome à cellules claires (HCC) après une néphrectomie
Protocole ID	MK-6482-022
ClinicalTrials.gov ID	NCT05239728
Type(s) de cancer	Rein
Phase	Phase III
Type étude	Clinique
Médicament	Belzutifan + pembrolizumab versus placebo + pembrolizumab
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
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Statut	Fermé
Date d'activation	15-12-2022
But étude	The purpose of this study is to assess the efficacy and safety of oral belzutifan (MK-6482) plus intravenous (IV) pembrolizumab (MK-3475) compared to placebo plus pembrolizumab, in the adjuvant treatment of Clear Cell Renal Cell Carcinoma (ccRCC) post nephrectomy.The primary study hypothesis is that belzutifan plus pembrolizumab is superior to placebo plus pembrolizumab with respect to disease-free survival (DFS).

Critères d'éligibilité	The main inclusion and exclusion criteria include but are not limited to the following: Inclusion Criteria:
	• Has a histologically or cytologically confirmed diagnosis of RCC with clear cell component per American Joint Committee on Cancer (AJCC) (8th Edition), with or without sarcomatoid features
	• Has intermediate-high risk, high risk, or M1 no evidence of disease (NED) RCC as defined by the following pathological tumor-node metastasis and tumor grading:
	  • Intermediate-high risk RCC: pT2, Grade 4 or sarcomatoid, N0, M0; pT3, any grade, N0, M0
	  • High risk RCC: pT4, any Grade N0, M0; pT any stage, any Grade, N+, M0
	  • M1 NED RCC participants who present not only with the primary kidney tumor but also solid, isolated, soft tissue metastases that can be completely resected at one of the following: the time of nephrectomy (synchronous) or, ≤2 years from nephrectomy (metachronous)
	• Has undergone complete resection of the primary tumor (partial or radical nephrectomy) and complete resection of solid, isolated, soft tissue metastatic lesion(s) in M1 NED participants
	• Must have undergone a nephrectomy and/or metastasectomy ≤12 weeks prior to randomization
	• Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 10 days before randomization.
	• Male participants must agree to continue contraception at least 7 days after the last dose of

	belzutifan/placebo • Female participants of childbearing potential must be willing to use an adequate method of contraception, for the course of the study through 120 days after the last dose of pembrolizumab or at least 30 days after last dose of belzutifan/placebo, whichever occurs last • Has adequate organ function
Critères d'exclusion	• Has had a major surgery, other than nephrectomy plus resection of preexisting metastases for M1 NED participants, within 4 weeks prior to randomization • Has a pulse oximeter reading <92% at rest, requires intermittent supplemental oxygen, or requires chronic supplemental oxygen • Has clinically significant cardiovascular disease within 6 months from first dose of study intervention • Has other clinically significant disorders such as: serious active nonhealing wound/ulcer/bone fracture; requirement for hemodialysis or peritoneal dialysis • Has preexisting brain or bone metastatic lesions • Has received prior systemic therapy for RCC • Has received prior radiotherapy for RCC • Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention; administration of killed vaccines are allowed • Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy • Has a known additional malignancy (other than RCC treated with nephrectomy and/or metastasectomy) that is progressing or has required active treatment within the past 3 years • Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids, or immunosuppressive drugs); replacement therapy is allowed • Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease • Has an active infection, requiring systemic therapy • Has a known history of human immunodeficiency virus (HIV) infection, a known history of Hepatitis B or known active Hepatitis C virus infection • Has had an allogenic tissue/solid organ transplant