Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants With Renal Cell Carcinoma
Protocole ID	V940-004
ClinicalTrials.gov ID	NCT06307431
Type(s) de cancer	Rein
Phase	Phase II
Type étude	Clinique
Médicament	V940 + Pembrolizumab versus Placebo + Pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Louis Lacombe
Coordonnateur	Marilyn Savard 418-525-4444 poste 67703
Statut	Actif en recrutement
Date d'activation	10-04-2024
But étude	The primary objective of the study is to compare V940 plus pembrolizumab to placebo plus pembrolizumab with respect to disease-free survival (DFS) as assessed by the investigator. The primary hypothesis is that V940 plus pembrolizumab is superior to placebo plus pembrolizumab with respect to DFS.
Critères d'éligibilité	• Has histologically or cytologically confirmed diagnosis of renal cell carcinoma (RCC) with clear cell or papillary histology. • 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 Gr4, N0, M0; pT3 Gr3/4, N0, M0 • High-risk RCC: pT4, N0, M0; pT any stage, N1, 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 1 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 and recovered from surgery and any post-operative complications before randomization. • Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days before randomization.

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 residual thrombus post nephrectomy in the vena renalis or vena cava. • Received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization. • Received prior radiotherapy within 2 weeks of start of study intervention, or radiation-related toxicities, requiring corticosteroids. • Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines is allowed. • Received prior treatment with a cancer vaccine. • Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy. • Has a known additional malignancy that is progressing or has required active treatment within the past 3 years. • Has a history of brain or bone metastatic lesions. • Has severe hypersensitivity to study medication or any of the substances used to prepare the study medication. • Has an active autoimmune disease that has required systemic treatment in the past 2 years. • 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. • History of allogeneic tissue/solid organ transplant. • Has not adequately recovered from major surgery or has ongoing surgical complications.