Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Phase III, Open Label, Randomised, 3-Arm, Multi-Centre Study of Savolitinib Plus Durvalumab Versus Sunitinib and Durvalumab Monotherapy in MET-Driven, Unresectable and Locally Advanced or Metastatic Papillary Renal Cell Carcinoma
Protocole ID	SAMETA
ClinicalTrials.gov ID	NCT05043090
Type(s) de cancer	Rein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Savolitinib + durvalumab versus sunitinib
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
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Statut	Actif en recrutement
Date d'activation	12-10-2022
But étude	A clinical trial to compare the effectiveness of savolitinib plus durvalumab versus sunitinib in MET-driven (hepatocyte growth factor receptor), unresectable and locally advanced or metastatic PRCC (Papillary Renal Cell Carcinoma). This is a Phase III, randomised, open label, 3 arm, multi-centre, international study assessing the efficacy and safety of savolitinib plus durvalumab compared with sunitinib in participants with MET-driven (without co-occurring FH mutations), unresectable and locally advanced or metastatic PRCC, who have not received any prior systemic anti-cancer therapy in the metastatic setting. The study will also investigate the contribution of durvalumab to the savolitinib plus durvalumab combinationApproximately 200 participants will be randomised in a 2:1:1 ratio to one of the following intervention groups: savolitinib (600mg, oral, once daily) plus durvalumab (1500mg IV Q4W), sunitinib (50mg, oral, once daily for 4 consecutive weeks, followed by a sunitinib-free interval of 2-weeks, Q6W), or durvalumab monotherapy (1500mg IV Q4W). Participants will continue to receive study intervention until objective radiological PD per RECIST 1.1 is assessed by the investigator, unacceptable toxicity occurs, consent is withdrawn or another discontinuation criterion is met. Depending on the preferred subsequent therapy, participants randomised to the durvalumab monotherapy arm will be eligible to switch to receive savolitinib in combination with durvalumab at the time of objective radiological PD assessed by BICR per RECIST 1.1, without any intervening systemic anti-cancer therapy following discontinuation of durvalumab monotherapy.

Critères d'éligibilité	• Histologically confirmed unresectable and locally advanced or metastatic PRCC • PRCC must be centrally confirmed as MET-driven using a sponsor-designated central laboratory validated NGS assay • No prior systemic anti-cancer treatment in the metastatic setting; no prior exposure to MET inhibitors, Durvalumab or Sunitinib in any setting • Karnofsky Score >70 • At least one lesion, not previously irradiated, that can be accurately measured at baseline • Adequate organ and bone marrow function • Life expectancy ≥12weeks at Day 1
Critères d'exclusion	• History of liver cirrhosis of any origin and clinical stage; or history of other serious liver disease or chronic disease with relevant liver involvement, with or without normal LFTs • Spinal cord compression or brain metastases, unless asymptomatic and stable on treatment for at least 14 days prior to study intervention • Active or prior cardiac disease (within past 6 months) or clinically significant ECG abnormalities and/or factors/medications that may affect QT and/or QTc intervals • Active infection including HIV, TB, HBV and HCV • Active or prior documented autoimmune or inflammatory disorders • Receipt of live attenuated vaccine within 30 days prior to the first dose of study intervention