Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Étude de phase III, contrôlée, à répartition aléatoire et à double insu comparant le cabozantinib en association avec le nivolumab et l'ipilimumab au nivolumab et à l'ipilimumab chez des sujets atteints d'un hypernéphrome métastatique ou au stade avancé à risque intermédiaire ou faible n'ayant jamais été traité
Protocole ID	XL184-313 (COSMIC-313)
ClinicalTrials.gov ID	NCT03937219
Type(s) de cancer	Rein
Phase	Phase III
Type étude	Traitement
Médicament	Cabozantinib avec Nivolumab et Ipilimumab vs Nivolumab et Ipilimumab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Wilson Miller
Coordonnateur	Ralph Waked 514-340-8222 poste 26823
Statut	Fermé
But étude	This is a multicenter, randomized, double-blinded, controlled Phase 3 trial of cabozantinib in combination with nivolumab and ipilimumab versus nivolumab and ipilimumab in combination with matched placebo. The primary objective of this study is to evaluate the effect of cabozantinib in combination with nivolumab and ipilimumab ("triplet") on the duration of progression-free survival (PFS) versus nivolumab and ipilimumab. A secondary objective is to evaluate the effect of triplet combination on the duration of overall survival (OS).
Critères d'éligibilité	• Histologically confirmed advanced (not amenable to curative surgery or radiation therapy) or metastatic (AJCC Stage IV) renal cell carcinoma with a clear-cell component. • Intermediate- or poor-risk RCC as defined by International Metastatic RCC Database Consortium (IMDC) criteria. • Measurable disease per RECIST 1.1 as determined by the Investigator. • Karnofsky Performance Status (KPS) ≥ 70%. • Adequate organ and marrow function.
Critères d'exclusion	• Prior systemic anticancer therapy for unresectable locally advanced or metastatic RCC including investigational agents. • Uncontrolled, significant intercurrent or recent illness including, but not limited to serious cardiovascular disorders (including uncontrolled hypertension defined as sustained blood pressure (BP) > 150 mm Hg systolic or > 90 mm Hg diastolic despite optimal antihypertensive treatment), GI disorders associated with high risk for perforation or fistula formation, tumors invading GI tract, bowel obstruction, intra-abdominal abscess, clinically significant bleeding events, cavitating pulmonary lesions, or lesions invading major pulmonary blood vessels. • Other clinically significant disorders such as: • i. Autoimmune disease that has been symptomatic or required treatment within the past two years from the date of randomization. • ii. Any condition requiring systemic treatment with either corticosteroids (> 10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of randomization. iii. Active infection requiring systemic treatment. Acute or chronic hepatitis B or

C infection, known human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)-related illness, or known positive test for tuberculosis infection where there is clinical or radiographic evidence of active myobacterial infection.

- Major surgery (eg, nephrectomy, GI surgery, removal or biopsy of brain metastasis) within 4 weeks prior to randomization. Minor surgeries within 10 days prior to randomization. Subjects must have complete wound healing from major or minor surgery before randomization.
- Any other active malignancy at time of randomization or diagnosis of another malignancy within 3 years prior to randomization that requires active treatment, except for locally curable cancers that have been apparently cured, such as basal or squamous cell skin cancer, superficial bladder cancer, or carcinoma in situ of the prostate, cervix, or breast.