Essai Clinique

Généré le 27 avr. 2024 à partir de

Titre	Étude ouverte de phase III multicentrique, internationale et à répartition aléatoire sur le durvalumab en association avec le traitement par le bacille de Calmette-Guérin (BCG) comparativement au traitement par le BCG seul chez des patients atteints d'un cancer de la vessie sans envahissement musculaire n'ayant jamais été traités par le BCG
Protocole ID	POTOMAC
ClinicalTrials.gov ID	NCT03528694
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Type étude	Traitement
Médicament	Durvalumab et Bacillus Calmette-Guerin
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Fred Saad
Coordonnateur	Amal Nadiri 514-890-8000 poste 26074
Statut	Fermé
But étude	This is a randomized, open-label, multi-center, global, phase III study to determine the efficacy and safety of Durvalumab + BCG combination therapy in the treatment of patients with non-muscle-invasive bladder cancer.
Critères d'éligibilité	• Aged at least 18 years • BCG-naïve patients. • Documented evidence of high-risk transitional cell bladder carcinoma stages T1 tumor, High grade/G3 tumor, CIS, or multiple and recurrent and large (with diameter of largest evaluable node ≥3 cm) tumors (all conditions must be met in this point) • Complete resection of all Ta/T1 papillary disease. • No prior radiotherapy to the bladder. • No prior exposure to immune-mediated therapy of cancer.
Critères d'exclusion	• Evidence of muscle-invasive, locally advanced, metastatic, and/or extra vesical bladder cancer (ie, T2, T3, T4, and / or stage IV). • Concurrent extravesical (ie, urethra, ureter, or renal pelvis), non-muscle-invasive transitional cell carcinoma of the urothelium. • Previous investigational product (IP) assignment in the present study • Any concurrent chemotherapy, IP, biologic, or hormonal therapy for cancer treatment. • Active or prior documented autoimmune or inflammatory disorders (eg, colitis, Crohn's disease, Graves' disease, rheumatoid arthritis etc.) • History of another primary malignancy • Active infection including TB, HBV, HCV and HIVActive infection. • Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab.