Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Étude globale ouverte de phase III, multi centrique à répartition aléatoire, visant à determiner l'éfficacité et la sécurité du durvalumab en combinaison avec gemcitabine + cisplatine en traitement néo-adjuvant suivi de durvalumab seul en traitement adjuvant chez les patients ayant un cancer de la vessie disséminé dans les muscles
Protocole ID	NIAGARA
ClinicalTrials.gov ID	NCT03732677
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Gemcitabine, Cisplatine et Durvalumab
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dr Michel Pavic
Coordonnateur	Anick Champoux 819-346-1110 poste 12811
Statut	Fermé
But étude	Global Study to Determine the Efficacy and Safety of Durvalumab in Combination with Gemcitabine+Cisplatin for Neoadjuvant Treatment and Durvalumab Alone for Adjuvant Treatment in Patients with Muscle-Invasive Bladder Cancer
Critères d'éligibilité	• Patient resectable muscle-invasive bladder cancer with clinical stage T2N0M0-T4aN0M0 with transitional cell histology • Patients must be planning to undergo a radical cystectomy at the time of randomization • Patients who have not received prior systemic chemotherapy or immunotherapy for treatment of MIBC • ECOG performance status of 0 or 1 • Must have a life expectancy of at least 12 weeks at randomization
Critères d'exclusion	• Evidence of lymph node or metastatic disease at time of screening. • Prior pelvic radiotherapy treatment within 2 years of randomization to study • Prior exposure to immune-mediated therapy (with exclusion of Bacillus-Calmette Guerin [BCG]), including but not limited to other anti-CTLA-4, anti-PD-1, anti PD-L1, or anti-PD-L2 antibodies. • Current or prior use of immunosuppressive medication within 14 days before the first dose of investigational product (IP). The following are exceptions to this criterion: Intranasal, inhaled, topical steroids, or local steroid injections (eg, intra articular injection); Systemic corticosteroids at physiologic doses not to exceed 10 mg/day of prednisone or its equivalent; Steroids as premedication for hypersensitivity reactions (eg, CT scan premedication) • Receipt of live attenuated vaccine within 30 days prior to the first dose of IP. • Uncontrolled intercurrent illness • Active infection including Tuberculosis, Hepatitis B, Hepatitis C, and Human Immunodeficiency