Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	Étude de phase III à répartition aléatoire et à double insu visant à évaluer l'association pembrolizumab péri-opératoire (MK-3475) + chimiothérapie néoadjuvante par rapport à l'association placebo péri-opératoire + chimiothérapie néoadjuvante chez des participants admissibles au cisplatine atteints d'un cancer de la vessie avec envahissement musculaire
Protocole ID	KEYNOTE-866
ClinicalTrials.gov ID	NCT03924856
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Médicament	Pembrolizumab périopératoire + chimiothérapie néoadjuvante
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Yves Fradet
Coordonnateur	Marilyn Savard 418-525-4444 poste 20414
Statut	Fermé
But étude	A global study to evaluate peri-operative pembrolizumab with chemotherapy versus placebo to pembrolizumab plus chemotherapy in cisplatin eligible patients.
Critères d'éligibilité	• Have a histologically confirmed diagnosis of muscle invasive bladder cancer (T2-T4aN0M0) with predominant (≥50%) urothelial histology (histology and presence of muscle invasion to be confirmed by BICR): Participants with mixed histology are eligible provided the urothelial component is ≥50%. • Participants whose tumors contain any neuroendocrine component are not eligible. • Urothelial carcinomas not originating from the bladder (e.g., upper tract [ureters, renal pelvis], urethra) are not eligible. • Have clinically non-metastatic bladder cancer (N0M0) determined by imaging (computed tomography (CT) chest or magnetic resonance imaging (MRI) of the abdomen/pelvis. • Be deemed eligible for RC + PLND by his/her urologist and/or oncologist and agree to undergo curative intent standard RC + PLND (including prostatectomy if applicable). • Have a transurethral resection (TUR) of a bladder tumor that is submitted and adequate to determine histology, muscle invasion, and PD-L1 status by central pathology vendor. • Have Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • Have demonstrated adequate organ function.
Critères d'exclusion	• Has a known additional malignancy that is progressing or has required active anti-cancer treatment ≤3 years of study randomization with certain exceptions. • Has received any prior systemic anti-neoplastic treatment for MIBC. • Is cisplatin-ineligible, as defined by meeting any one of the study criteria. • Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., CTLA-4, OX-40, CD137). • Has received therapy with hematopoietic growth factor such as granulocyte-colony stimulating

factor (G-CSF) or granulocyte-monocyte-colony stimulating factor(GM-CSF) in 14 days prior to randomization.
- Has received prior systemic anti-cancer therapy including investigational agents within 3 years of randomization.
- Has received any prior radiotherapy to the bladder.
- Has received a live vaccine within 30 days prior to the first dose of study drug.
- Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study intervention.
- Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study drug.
- Has hypersensitivity to monoclonal antibodies (mAbs, including pembrolizumab) and/or any of their excipients.
- Has severe hypersensitivity (≥Grade 3) to cisplatin and/or gemcitabine and any of their excipients.
- Has an active autoimmune disease that has required systemic treatment in past 2 years
- Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis.
- Has an active infection requiring systemic therapy.