Essai Clinique

Généré le 11 mai 2024 à partir de

Titre	Étude clinique de phase II visant à étudier l'efficacité et l'innocuité du pembrolizumab chez les sujets atteints d'un cancer de la vessie métastatique sans envahissement musculaire à risque élevé, qui ne répond pas au traitement par le bacille de Calmette-Guérin (BCG)
Protocole ID	MK-3475-057/KEYNOTE-057
ClinicalTrials.gov ID	NCT02625961
Type(s) de cancer	Vessie/urothélial
Phase	Phase II
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Michele Lodde
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Statut	Actif en recrutement
But étude	In this study, participants with high risk non-muscle-invasive bladder cancer (NMIBC) unresponsive to Bacillus Calmette Guerin (BCG) therapy and who are considered ineligible for or have refused to undergo radical cystectomy, will receive pembrolizumab therapy. The primary study hypothesis is that treatment with pembrolizumab will result in a clinically meaningful response.
Critères d'éligibilité	• Histologically-confirmed diagnosis of high risk non-muscle-invasive (T1, high grade Ta and / or carcinoma in situ) transitional cell carcinoma of the bladder (mixed histology tumors allowed if transitional cell histology is predominant histology) • Absence of resectable disease after at least 2 cystoscopy /transurethral resection (TURBT) procedures (residual CIS acceptable) • BCG-unresponsive high risk non-muscle-invasive bladder cancer after treatment with adequate BCG therapy • Ineligible for radical cystectomy or refusal of radical cystectomy • Available tissue from a newly obtained core biopsy of a tumor lesion not previously irradiated • Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 • Adequate organ function • Female participants of childbearing potential have a negative urine or serum pregnancy test and must be willing to use an adequate method of contraception • Male participants must be willing to use an adequate method of contraception
Critères d'exclusion	• Muscle-invasive, locally advanced nonresectable, or metastatic urothelial carcinoma (i.e., T2, T3, T4, and / or stage IV) • Concurrent extra-vesical (i.e., urethra, ureter, or renal pelvis) non-muscle invasive transitional cell carcinoma of the urothelium • Currently participating or has participated in a study of an investigational agent and received study therapy or received investigational device within 4 weeks prior to the first dose of study treatment • Received intervening intravesical chemotherapy or immunotherapy from the time of most recent cystoscopy / TURBT to starting study treatment • Received prior chemotherapy, targeted small molecule therapy, or radiation therapy within 2

weeks prior to starting study treatment or not recovered from adverse events due to a previously administered agent
- Known additional malignancy that is progressing or requires active treatment excepting basal cell carcinoma of the skin, squamous cell carcinoma of the skin that has undergone potentially curative therapy or in situ cervical cancer. A history of prostate cancer that was treated with definitive intent (surgically or through radiation therapy) is acceptable
- Active autoimmune disease that has required systemic treatment in the past 2 years
- Evidence of interstitial lung disease or active non-infectious pneumonitis
- Active infection requiring systemic therapy
- Pregnant or breastfeeding, or expecting to conceive within the projected duration of the trial through 120 days after the last dose of study treatment
- Prior therapy with an anti-programmed cell death 1 (PD-1), anti-PD-ligand 2 (L2) agent, or with an agent directed to another co-inhibitory T-cell receptor
- Known human immunodeficiency virus (HIV)
- Known active Hepatitis B or C infection
- Received a live virus vaccine within 30 days of planned start of study treatment