Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	Une étude clinique de phase III, randomisée, contrôlée par comparateur pour étudier l'efficacité et l'innocuité du Pembrolizumab (MK-3475) en combinaison avec la bacille de Calmette-Guerin (BCG) chez les participants avec un cancer de la vessie non-invasif sur le plan musculaire (CVNIM) à haut risque qui est persistant ou récidivant suivant une induction au BCG
Protocole ID	MK-3475-676
ClinicalTrials.gov ID	NCT03711032
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Stade	Récidive
Type étude	Traitement
Médicament	Pembrolizumab avec BCG
Institution	CIUSSS DU SAGUENAY – LAC-SAINT-JEAN HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
Investigateur principal	Dr Jean-Benoit Paradis
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Statut	Fermé
But étude	This study is designed to assess the antitumor efficacy and safety of pembrolizumab in combination with BCG, compared to BCG monotherapy, in participants with HR NMIBC that is persistent or recurrent following adequate BCG induction. The primary hypothesis is that the combination of pembrolizumab plus BCG has a superior complete response rate (CRR) as assessed by central pathology review compared to BCG in participants with carcinoma in situ (CIS).
Critères d'éligibilité	• Has histologically-confirmed diagnosis of non-muscle invasive (T1, high grade Ta and/or CIS) transitional cell carcinoma (TCC) of the bladder • Has been treated with one adequate course of BCG induction therapy for the treatment of HR NMIBC • Following adequate BCG induction therapy, must have persistent or recurrent HR NMIBC • Has undergone cystoscopy/ transurethral resection of bladder tumor (TURBT) to remove all resectable disease • Has provided tissue for biomarker analysis • Has Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 • Has adequate organ function • Male participants must agree to use approved contraception during the treatment period and for at least 120 days after the last dose of study treatment and refrain from donating sperm during this period • Female participants who are not pregnant, not breastfeeding, and either not a woman of child bearing potential (WOCBP) or are a WOCBP who agrees to use approved contraception during the treatment period and for at least 120 days after the last dose of study treatment

Critères d'exclusion	• Has persistent T1 disease following an induction course of BCG • Has muscle invasive (i.e., T2, T3, T4), locally advanced non-resectable or metastatic UC • Has concurrent extra-vesical (i.e., urethra, ureter, renal pelvis) non-muscle invasive TCC of the urothelium, concurrent upper tract involvement, or invasive prostatic TCC including T1 or greater disease, or ductal invasion • WOCBP who has a positive urine pregnancy test within 72 hours prior to randomization • Has received prior therapy with anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another co-inhibitory T-cell receptor • Has received prior systemic anti-cancer therapy including investigational agents within 4 weeks of start of study treatment • Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks of start of study treatment • Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days of start of study treatment • Has a known additional malignancy that is progressing or requires active treatment within the past 3 years • 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 one or more of the following contraindications to BCG: prior BCG sepsis or systemic infection, total bladder incontinence, or an adverse experience to a previous BCG instillation that resulted in treatment discontinuation and precludes retreating with BCG • Has an active infection requiring systemic therapy • Has a known history of human immunodeficiency virus (HIV) infection • Has a known history of Hepatitis B or known active Hepatitis C virus infection • Has evidence of active tuberculosis • Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 120 days after the last dose of trial treatment