Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	A Phase 3, Randomized, Study of Neoadjuvant and Adjuvant Nivolumab Plus NKTR-214, Versus Nivolumab Alone Versus Standard of Care in Participants With Muscle-Invasive Bladder Cancer (MIBC) Who Are Cisplatin Ineligible
Protocole ID	CA045-009
ClinicalTrials.gov ID	NCT04209114
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Type étude	Clinique
Médicament	Nivolumab plus NKTR-214 versus nivolumab seul
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE H HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
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Statut	Fermé
But étude	The purpose of the study is to see if treatment with nivolumab plus bempeg or nivolumab alone, before and after surgery to remove the bladder, is more effective than surgery alone in participants with muscle-invasive bladder cancer who are not able to receive cisplatin chemotherapy.
Critères d'éligibilité	• MIBC, clinical stage T2-T4a, N0, M0, diagnosed at transurethral resection of bladder tumor (TURBT) and confirmed by radiographic imaging. • Must be deemed eligible for Radical Cystectomy (RC) by urologist, and must agree to undergo RC. For arms A and B, participants must agree to undergo RC after completion of neoadjuvant therapy. • Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 • Cisplatin-ineligible participants will be defined by any one of the following criteria: i) Impaired renal function (glomerular filtration rate [GFR] ≥ 30 but < 60 mL/min) ii) GFR should be assessed by direct measurement (ie, creatinine clearance) or, if not available, by calculation from serum/plasma creatinine (Cockcroft-Gault formula) iii) Common Terminology Criteria for Adverse Events (CTCAE) version 5, ≥ Grade 2 hearing loss (assessed per local SOC). iv) CTCAE version 5, ≥ Grade 2 peripheral neuropathy. • Documented Left Ventricular Ejection Fraction (LVEF) more than 45% • Women and men must agree to follow specific methods of contraception, if applicable
Critères d'exclusion	• Clinical evidence of pathologic lymph node (LN) or metastatic bladder cancer. • Prior systemic therapy, radiation therapy, or surgery for bladder cancer other than TURBT or biopsies is not permitted. Prior Bacillus Calmette-Guerin (BCG) or other intravesicular treatment of non-muscle invasive bladder cancer (NMIBC) is permitted if completed at least 6 weeks prior to initiating study treatment. • Evidence of urothelial carcinoma (UC) in upper urinary tracts (ureters or renal pelvis) or history of previous MIBC • History of pulmonary embolism (PE), deep vein thrombosis (DVT), or prior clinically significant venous or non-CVA(cerebrovascular accident)/TIA (Transient ischemic attack) arterial thromboembolic event

	Other protocol-defined inclusion/exclusion criteria apply