Essai Clinique

Généré le 14 mai 2024 à partir de

Titre	Étude multicentrique de phase III à répartition aléatoire visant à évaluer l'efficacité du système TAR-200 utilisé en association avec du cétrélimab par rapport à celle d'une chimioradiothérapie concomitante chez des participants atteints d'un carcinome urothélial de la vessie avec envahissement musculaire et ne bénéficiant pas d'une cystectomie radicale
Protocole ID	SunRISe-2
ClinicalTrials.gov ID	NCT04658862
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Type étude	Clinique
Médicament	TAR-200 avec cetrelimab versus chimioradiothérapie concomitante
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Louis Lacombe
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Statut	Actif en recrutement
Date d'activation	15-08-2023
But étude	The purpose of study is to compare bladder intact-event free survival (BI-EFS) in participants receiving TAR-200 in combination with cetrelimab versus concurrent chemoradiotherapy. The TAR-200 is an investigational drug delivery system. Cetrelimab (JNJ-63723283) is a fully human immunoglobulin G4 (IgG4) kappa monoclonal antibody (mAb) that binds programmed cell death protein 1 (PD-1). Study consists of screening phase of 42 days, treatment phase and follow up phase. The total duration of study will be up to 8 years. Efficacy evaluation includes disease assessment (Cystoscopy/TURBT Biopsy/Pathology) and Patient Reported Outcomes (Quality of Life Assessments) and safety assessments includes vital sign measurements, 12-lead electrocardiogram (ECG), physical examinations, clinical laboratory tests, cystoscopic examination, anti-drug antibody (ADA) assessments, concomitant treatments/procedures and adverse event monitoring.
Critères d'éligibilité	• Ineligible for or have elected not to undergo radical cystectomy • All adverse events associated with any prior surgery and/or intravesical therapy must have resolved to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 Grade less than (<) 2 prior to randomization • Eastern Cooperative Oncology Group (ECOG) performance status Grade 0, 1, or 2 • Thyroid function tests within normal range or stable on hormone supplementation per investigator assessment. • Adequate bone marrow, liver, and renal function: Bone marrow function (without the support of cytokines or erythropoiesis-stimulating agent in preceding two weeks): Absolute neutrophil count (ANC) greater than or equal to (>=) 1,500/cubic millimeters (mm^3); Platelet count >=80,000/mm^3; Hemoglobin >=9.0 grams per deciliter (g/dL); Liver function: (Total bilirubin less than or equal to (<=) 1.5 * upper limit of normal (ULN) or direct bilirubin <= ULN for participants with total bilirubin levels greater than (>)1.5*ULN (except participants with Gilbert's Syndrome, who must have a total bilirubin < 3.0 mg/dL), and Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) less than or equal to (<=) 2.5* institutional ULN); Renal function: Creatinine clearance >40 mL/min using the Cockcroft-Gault formula

Critères d'exclusion	• Must not have had urothelial carcinoma or histological variant at any site outside of the urinary bladder. Ta/T1/Carcinoma in situ (CIS) of the upper urinary tract (including renal pelvis and ureter) is allowable if treated with complete nephrouretrectomy more than 24 months prior to initiating study • Must not have diffuse CIS based on cystoscopy and biopsy. Diffuse, or multi-focal, CIS is defined as the presence of at least 4 distinct CIS lesions in the bladder at the time of the Screening re-TURBT • Participants must not have evidence of cT4b, or N1-3, or M1 disease based on local radiology staging (chest, abdomen, and pelvis must be performed using Computed tomography [CT] or Magnetic resonance imaging [MRI]) within 42 days prior to randomization • Presence of any bladder or urethral anatomic feature that, in the opinion of the investigator, may prevent the safe placement, indwelling use, or removal of TAR 200 • Evidence of bladder perforation during diagnostic cystoscopy