Essai Clinique

Généré le 09 mai 2024 à partir de

Titre	A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer
Protocole ID	VOLGA
ClinicalTrials.gov ID	NCT04960709
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Type étude	Clinique
Médicament	Durvalumab en association avec tremelimumab et enfortumab védotine ou Durvalumab en association avec enfortumab védotine
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
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Statut	Actif en recrutement
Date d'activation	24-01-2024
But étude	A global phase 3, multicenter, randomized, trial, to Determine the Efficacy and Safety of Durvalumab in combination with Tremelimumab and Enfortumab Vedotin or Durvalumab in combination with Enfortumab vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or who refuse Cisplantin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer.The goal of the study is to explore the triplet combination of Durvalumab, Tremelimumab and Enfortumab Vedotin in terms of efficacy and safety compared to the current Standard Of Care (SOC). Volga trial consists of two parts: Safety Run-In and Main Study. In total the study aims to enroll approximately 830 patients, who will receive triplet combination, duplet combination of Durvalumab and Enfortumab vedotin or currently approved SOC in the main trial. In the main part of the trial there is two out of three chances of being on a treatment arm and the treatment is assigned at random by a computer systemIn this trial patients in the two treatment arms will receive either 3 cycles of neoadjuvant Durvalumab + Tremelimumab + Enfortumab Vedotin or Durvalumab + Enfortumab vedotin and after surgery both treatment arms will continue with adjuvant Durvalumab.
Critères d'éligibilité	• Histologically or cytologically documented muscle-invasive UC of the bladder. • Participants with transitional cell and mixed transitional/non-transitional cell histologies; • Participants with MIBC clinical tumor (T) stage T2-T4aN0/1M0 or UC of the bladder with clinical state T1N1M0. • Participants should also have not received prior systemic chemotherapy or immunotherapy for the treatment of MIBC or bladder UC. • Medically fit for cystectomy and able to receive neoadjuvant therapy; • Patients who have not received prior systemic chemotherapy or immunotherapy for treatment of MIBC; • ECOG performance status of 0,1,2 at enrollment. • Availability of tumor sample prior to study entry; • Must have a life expectancy of at least 12 weeks at randomization.

	• Cisplatin-ineligible, as defined by any of the following criteria (based on Galsky et al 2011) OR Refuse cisplatin based chemotherapy (must be documented in the medical records)
Critères d'exclusion	• Evidence of lymph node (N2+) or metastatic TCC/UC disease at the time of screening. • Active infection • Uncontrolled intercurrent illness • Prior exposure to immune-mediated therapy (with exclusion of Bacillus-Calmette Guerin [BCG]), including but not limited to other anti-CTLA-4, anti--PD-1, anti PD-L1, or anti-PD-L2 antibodies. • Current or prior use of immunosuppressive medication within 14 days before the first dose of IPs.