Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude ouverte de phase III, à répartition aléatoire, évaluant l'enfortumab vedotine en combinaison avec pembrolizumab ± chimiothérapie comparativement à la chimiothérapie seule chez les sujets atteints d'un cancer urothélial localement avancé ou métastatique jamais traité
Protocole ID	SGN22E-003 (EV-302)
ClinicalTrials.gov ID	NCT04223856
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Enfortumab vedotine en association avec le pembrolizumab ± chimiothérapie versus chimiothérapie seule
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Cristiano Ferrario
Coordonnateur	Fatima Razazeinou 514-340-8222 poste 25509
Statut	Fermé
But étude	This study is being done to see how well two drugs (enfortumab vedotin and pembrolizumab) work together to treat patients with urothelial cancer. The study will compare these drugs to other drugs that are usually used to treat this cancer (standard of care). The patients in this study will have cancer that has spread from their urinary system to other parts of their body.

Critères d'éligibilité	• Histologically documented, unresectable locally advanced or metastatic urothelial carcinoma
	• Measurable disease by investigator assessment according to RECIST v1.1
	  • Participants with prior definitive radiation therapy must have measurable disease per RECIST v1.1 that is outside the radiation field or has demonstrated unequivocal progression since completion of radiation therapy
	• Participants must not have received prior systemic therapy for locally advanced or metastatic urothelial carcinoma with the following exceptions:
	  • Participants that received neoadjuvant chemotherapy with recurrence >12 months from completion of therapy are permitted
	  • Participants that received adjuvant chemotherapy following cystectomy with recurrence >12 months from completion of therapy are permitted
	• Must be considered eligible to receive cisplatin- or carboplatin-containing chemotherapy, in the investigator's judgment
	• Archival tumor tissue comprising muscle-invasive urothelial carcinoma or a biopsy of metastatic urothelial carcinoma must be provided for PD-L1 testing prior to randomization
	• Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0, 1, or 2
	• Adequate hematologic and organ function

Critères d'exclusion	• Previously received enfortumab vedotin or other monomethyl auristatin E (MMAE)-based antibody-drug conjugate (ADCs) • Received prior treatment with a programmed cell death ligand-1 (PD-(L)-1) inhibitor for any malignancy, including earlier stage urothelial cancer (UC), defined as a PD-1 inhibitor or PD-L1 inhibitor • Received prior treatment with an agent directed to another stimulatory or co inhibitory T-cell receptor • Received anti-cancer treatment with chemotherapy, biologics, or investigational agents not otherwise prohibited by exclusion criterion 1-3 that is not completed 4 weeks prior to first dose of study treatment • Uncontrolled diabetes • Estimated life expectancy of less than 12 weeks • Active central nervous system (CNS) metastases • Ongoing clinically significant toxicity associated with prior treatment that has not resolved to ≤ Grade 1 or returned to baseline • Currently receiving systemic antimicrobial treatment for active infection (viral, bacterial, or fungal) at the time of randomization. Routine antimicrobial prophylaxis is permitted. • Known active hepatitis B, active hepatitis C, or human immunodeficiency virus (HIV) infection. • History of another invasive malignancy within 3 years before the first dose of study drug, or any evidence of residual disease from a previously diagnosed malignancy • Documented history of a cerebral vascular event (stroke or transient ischemic attack), unstable angina, myocardial infarction, or cardiac symptoms consistent with New York Heart Association (NYHA) Class IV within 6 months prior to randomization • Receipt of radiotherapy within 2 weeks prior to randomization • Received major surgery (defined as requiring general anesthesia and >24 hour inpatient hospitalization) within 4 weeks prior to randomization • Known severe (≥ Grade 3) hypersensitivity to any enfortumab vedotin excipient contained in the drug formulation of enfortumab vedotin • Active keratitis or corneal ulcerations • History of autoimmune disease that has required systemic treatment in the past 2 years • History of idiopathic pulmonary fibrosis, organizing pneumonia, drug induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan • Prior allogeneic stem cell or solid organ transplant • Received a live attenuated vaccine within 30 days prior to randomization