Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants With HER2 Overexpressing Gastric Cancer
Protocole ID	DESTINY-Gastric03
ClinicalTrials.gov ID	NCT04379596
Type(s) de cancer	Estomac
Phase	Phase I-II
Type étude	Clinique
Médicament	Trastuzumab Deruxtecan
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
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Statut	Fermé
But étude	DESTINY-Gastric03 will investigate the safety, tolerability, pharmacokinetics, immunogenicity, and preliminary antitumor activity of trastuzumab deruxtecan (T-DXd) alone or in combination with chemotherapy and/or durvalumab in HER2-positive advanced/metastatic gastric/gastroesophageal junction (GEJ) adenocarcinoma patients. Study hypotheses: Combination of T-DXd with cytotoxic chemotherapy and/or durvalumab administered to subjects at the recommended phase 2 dose will show manageable safety and tolerability and preliminary anti-tumor efficacy so as to permit further clinical testing. T-DXd in combination with cytotoxic chemotherapy or immune checkpoint inhibitor administered to HER2-positive gastric/GEJ cancer patients who have not received prior treatment for advanced/metastatic disease will show preliminary evidence of anti-tumour activity and the potential to become a therapeutic option for this patient population.
Critères d'éligibilité	• Male and female participants must be at least 18 years of age • Disease Characteristics: Locally advanced, unresectable, or metastatic disease Pathologically documented adenocarcinoma of the stomach or GEJ with HER2 overexpression (IHC 3+ or ICH 2+/ISH+) • For Part 1, progression on or after at least one prior trastuzumab containing Regimen. For Part 2, previously untreated for unresectable or metastatic adenocarcinoma of the stomach or GEJ with HER2 overexpression. • Has measurable target disease assessed by the Investigator based on RECIST version 1.1 • Has protocol defined adequate organ function including cardiac, renal and hepatic function • If of reproductive potential, agrees to use a highly effective form of contraception or avoid intercourse during and upon completion of the study.

Critères d'exclusion	• History of active primary immunodeficiency, known HIV, active HBV or HCV infection. • Uncontrolled intercurrent illness. • History of non-infectious pneumonitis/ILD, current ILD, or where suspected ILD that cannot be ruled out by imaging at screening. • Lung-specific intercurrent clinically significant severe illnesses. • Uncontrolled infection requiring intravenous (IV) antibiotics, antivirals, or antifungals. • Pleural effusion, ascites or pericardial effusion that requires drainage, peritoneal shunt, or Cell-free and Concentrated Ascites Reinfusion Therapy (CART). • Has spinal cord compression or clinically active central nervous system metastases.