Essai Clinique

Généré le 14 mai 2024 à partir de

Titre	Étude multicentrique ouverte de phase II visant à évaluer l'efficacité et l'innocuité du trastuzumab déruxtécan (T-DXd, DS-8201a) dans le traitement de certaines tumeurs exprimant HER2
Protocole ID	DESTINY-PanTumor02
ClinicalTrials.gov ID	NCT04482309
Type(s) de cancer	Tumeurs solides
Phase	Phase 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	
Investigateur principal	Dr Maxime Chénard-Poirier
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Statut	Actif en recrutement
But étude	Il s'agit d'une étude multicentrique ouverte de phase II à cohortes multiples, visant à évaluer l'efficacité et l'innocuité du trastuzumab déruxtécan (T-DXd) dans le traitement de certaines tumeurs exprimant HER2. Cette étude portera sur sept (7) cohortes spécifiques de la tumeur : cancer urothélial de la vessie, cancer des voies biliaires, cancer du col de l'utérus, cancer de l'endomètre, cancer de l'ovaire, cancer du pancréas et tumeurs rares. Hypothèse de l'étude : Le trastuzumab déruxtécan présentera une activité clinique et un profil risques-avantages favorable dans le traitement de certaines tumeurs solides exprimant HER2.

Critères d'éligibilité	• Locally advanced, unresectable, or metastatic disease based on most recent imaging.
	• The respective cohorts for patient inclusion are:
	  • Cohort 1: Biliary tract cancer
	  • Cohort 2: Bladder cancer
	  • Cohort 3: Cervical cancer
	  • Cohort 4: Endometrial cancer
	  • Cohort 5: Epithelial ovarian cancer
	  • Cohort 6: Pancreatic cancer
	  • Cohort 7: Rare tumors: This cohort will consist of patients with tumors that express HER2, excluding the tumors mentioned above, and breast, non-small cell lung cancer, gastric cancer, and colorectal cancer.
	• Progressed following prior treatment or who have no satisfactory alternative treatment option.
	• Prior HER2 targeting therapy is permitted.
	• HER2 expression for eligibility may be based on local or central assessment.
	• 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.

Critères d'exclusion	• 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 • Known Somatic DNA mutation of HER2 (ERBB2) without tumoral HER2 protein expression. • Primary diagnosis of adenocarcinoma of the breast, adenocarcinoma of the colon or rectum, adenocarcinoma of the gastric body or gastro-esophageal junction, or non-small cell lung cancer.