Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Une étude de détermination et d'expansion de la dose ouverte de phase Ib/II multicentrique, de type modulaire visant à examiner l'innocuité, la tolérance et l'activité antitumorale du trastuzumab deruxtecan (T-DXd) en association avec d'autres agents anticancéreux chez les patients atteints d'un cancer du sein métastatique HER2-positif.
Protocole ID	DB-07 (DESTINY-Breast07)
ClinicalTrials.gov ID	NCT04538742
Type(s) de cancer	Sein
Phase	Phase I-II
Stade	Métastatique
Type étude	Clinique
Médicament	Trastuzumab deruxtecan
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
Investigateur principal	Dre Julie Lemieux
Coordonnateur	Fanie Bourgault 418-525-4444 poste 82697
Statut	Fermé
But étude	DESTINY-Breast07 will investigate the safety, tolerability, and anti-tumour activity of trastuzumab deruxtecan (T-DXd) in combination with other anti-cancer agents in patients with HER2-positive Metastatic Breast Cancer
Critères d'éligibilité	• Patients must be at least 18 years of age • Pathologically documented breast cancer that: 1. Is advanced/unresectable (patients that can be treated with curative intent are not eligible) or metastatic 2. HER2-positive (IHC 3+ or IHC 2+/ISH+) based on local assessment 3. Is documented as hormone receptor-positive (estrogen or progesterone receptor) or negative in the metastatic setting • Patient must have adequate tumor sample for biomarker assessment • ECOG Performance Status of 0 or 1 • Part 1 1. Disease progression on or after the last systemic therapy prior to starting study treatment 2. At least 1 prior treatment line in metastatic setting required. • Part 2 (Modules 0 - 5) a) No prior lines of therapy for advanced/MBC allowed • Part 2 (Module 6 and 7) a) Zero or one prior lines of therapy for advanced/MBC allowed CNS Inclusion • Modules 0 - 5 Patients must have no brain metastases or stable brain metastases. • Module 6 and 7 Patients must have untreated brain metastases not needing local therapy or previously treated brain metastases that have progressed since prior local therapy

Critères d'exclusion	• Uncontrolled or significant cardiovascular disease • Active or prior documented (non-infectious) ILD/pneumonitis that required steroids, or suspected ILD/pneumonitis that cannot be ruled out by imaging at screening • Lung-specific intercurrent clinically significant illnesses • Uncontrolled infection requiring IV antibiotics, antivirals, or antifungals • Spinal cord compression or a history of leptomeningeal carcinomatosis • Prior treatment with immune checkpoint inhibitors • Prior treatment with an ADC containing a topoisomerase I inhibitor • Prior treatment with tucatinib CNS Exclusion • Modules 0 - 5: Has untreated brain metastasis • Module 6 and 7: Ongoing use of systemic corticosteroids for control of symptoms of brain metastases or brain lesion thought to require immediate local therapy