Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	A Phase 1b Multicentre, Open-label, Modular, Dose-finding and Dose-expansion Study to Explore the Safety, Tolerability, Pharmacokinetics and Anti-tumour Activity of Trastuzumab Deruxtecan (T-DXd) in Combination With Other Anti-cancer Agents in Patients With Metastatic HER2-low Breast Cancer
Protocole ID	DESTINY-Breast08
ClinicalTrials.gov ID	NCT04556773
Type(s) de cancer	Sein
Phase	Phase I
Stade	Métastatique
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 Vincent Castonguay
Coordonnateur	Maryse Gingras 418-691-5781
Statut	Fermé
But étude	This study is modular in design allowing assessment of the safety, tolerability, PK and preliminary anti-tumour activity of T-DXd in combination with other therapies. Combination-treatment modules will have 2 parts: a dose-finding phase (Part 1), and a dose expansion phase (Part 2); the Part 2 dose-expansion phase will use the RP2D determined in Part 1. The target population of interest in this study is patients with HER2-low (IHC 1+ or IHC 2+/ISH -) (as per ASCO/CAP 2018 guidelines) advanced/MBC. Part 1 of each module will enroll patients with locally confirmed HER2-low advanced/MBC in second-line or later (≥ 2L) settings Part 2 of each module will enroll patients with HER2-low MBC who have either not received prior treatment, or received only 1 prior treatment (depending on the module-specific exclusion criteria) for advanced/metastatic disease
Critères d'éligibilité	• Patients must be at least 18 years of age • Male or female patients who have pathologically documented breast cancer that: 1. Has a history of HER2-low expression, defined as IHC 2+/ISH- or IHC 1+ (ISH- or untested) with a validated assay 2. Is documented as HR+ (either ER and/or PgR positive [ER or PgR ≥1%]) or ER and PgR negative (ER and PgR <1%) per ASCO/CAP guidelines in the metastatic setting • Patient must have adequate tumor sample for biomarker assessment • ECOG Performance Status of 0 or 1 For patients with HR+ disease: Part 1: At least 1 prior treatment line of ET with or without a targeted therapy (such as CDK4/6, mTOR or PI3-K inhibitors), and at least 1 prior line of chemotherapy for MBC are required. Part 2: Only 1 prior treatment line of ET with or without a targeted therapy (such as CDK4/6, mTOR or PI3-K inhibitors) for MBC is allowed. No prior chemotherapy in the metastatic setting is allowed. Note there are no patients with HR+ disease in Part 2 of Modules 2 and 3.For patients with HR- disease: Part 1: At least 1 prior line of chemotherapy for MBC is required. Note there are no patients with HR- disease in Part 1 of Modules 4 and 5Part 2: For Module 2, no prior lines of therapy for MBC are allowed, and for Modules 1 and 3, only 1 prior line of chemotherapy for MBC is allowed. Note there are no patients with HR- disease in Part 2 of Modules 4 and 5.

Critères d'exclusion	• Uncontrolled intercurrent illness • Uncontrolled or siginificant cardiovascular disease • History of (non-infectious) ILD/pneumonitis that required steroids, has current ILD/pneumonitis, or where suspected ILD/pneumonitis cannot be ruled out by imaging at screening. • Lung-specific intercurrent clinically significant illnesses • Has spinal cord compression or clinically active central nervous system metastases • Active primary immunodeficiency • Uncontrolled infection requiring IV antibiotics, antivirals, or antifungals • Prior treatment with ADC that comprises of an exatecan derivative that is a topoisomerase I inhibitor.