Essai Clinique

Généré le 15 mai 2024 à partir de

Titre	A Phase II, Multicentre, Open-label, Master Protocol to Evaluate the Efficacy and Safety of Datopotamab Deruxtecan (Dato-DXd) as Monotherapy and in Combination With Anticancer Agents in Patients With Advanced/Metastatic Solid Tumours
Protocole ID	TROPION-PanTumor03
ClinicalTrials.gov ID	NCT05489211
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Datopotamab deruxtecan en monothérapie et en association avec des agents anticancéreux
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
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Statut	Actif en recrutement
Date d'activation	18-10-2023
But étude	This Phase II, open-label, uncontrolled, multicentre study evaluating the efficacy and safety of Dato-DXd as monotherapy (MONO) and in combination with anticancer agents (COMBO) in various advanced solid tumour types. This study has a modular design, as such a master protocol with independent substudies enables simultaneous evaluation of the safety profile, recommended Phase II dose (RP2D), and efficacy of Dato-DXd in multiple disease populations and treatment combinations. This study will evaluate various solid tumour types, including endometrial cancer (Substudy 1), gastric cancer (Substudy 2), metastatic castration-resistant prostate cancer (mCRPC) (Substudy 3), ovarian cancer (Substudy 4), and colorectal cancer (CRC) (Substudy 5) in the advanced or metastatic setting. Within each substudy, Dato-DXd will be evaluated as monotherapy (for all substudies except Substudy 2, (Gastric Cancer) and in combination with approved or novel anticancer agents that may be active in the tumour type being evaluated.(AZD5305, Durvalumab).
Critères d'éligibilité	• Male and female, ≥ 18 years • Histologically or cytologically documented advanced or metastatic malignancy. • At least 1 lesion not previously irradiated that qualifies as a RECIST 1.1 target lesion at baseline Substudy 3 (mCRPC) allows enrolment of participants with non measurable (by RECIST 1.1) bone metastatic disease. • Adequate bone marrow reserve and organ function within 7 days before randomization/treatment • Minimum life expectancy of 12 weeks

Critères d'exclusion	• Persistent toxicities caused by previous anticancer therapy, excluding alopecia, not yet improved to Grade ≤ 1 or baseline • Spinal cord compression or brain metastases unless treated • Leptomeningeal carcinomatosis • Clinically significant corneal disease • Active hepatitis or uncontrolled hepatitis B or C virus infection • Uncontrolled infection requiring IV antibiotics, antivirals or antifungals eg, prodromal symptoms • Significant cardiac diseases • History of non-infectious Interstitial lung disease (ILD)/pneumonitis that required steroids • Prior exposure to chloroquine/hydroxychloroquine without an adequate treatment washout period • Prior exposure to anticancer therapies without an adequate treatment washout period prior to enrolment • Prior treatment with TROP2-directed Anti-drug antibody ADC Antibody-drug conjugate (ADCs), other ADCs with deruxtecan payload • Severe hypersensitivity to Dato-DXd monoclonal antibodies polysorbate 80 or other monoclonal antibodies. • Pregnant, breastfeeding, planning to become pregnant.