Essai Clinique

Généré le 27 juil. 2024 à partir de

Titre	A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Patients With Hormone Receptor-Positive (HR+)/Human Epidermal Growth Factor Receptor 2 Negative (HER2-) (HER2 IHC0 or HER2-low [IHC 1+, IHC 2+/ISH-]) Inoperable, Locally Advanced, or Metastatic Breast Cancer and Have Received Endocrine Therapy
Protocole ID	ASCENT-07
ClinicalTrials.gov ID	NCT05840211
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Sacituzumab govitecan Versus traitement au choix du clinicien
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
Investigateur principal	Dr André Blais
Coordonnateur	Fanie Bourgault 418-525-4444 poste 82697
Statut	Actif en recrutement
Date d'activation	17-10-2023
But étude	The goal of this clinical study is to see if sacituzumab govitecan-hziy (SG) can improve life spans of people with HR+/HER2- metastatic breast cancer and their tumor does not grow or spread when compared to current available standard treatments, such as paclitaxel, nab-paclitaxel or capecitabine. The primary objective is to compare the effect of SG relative to the treatment of physician's choice (TPC) on progression-free survival (PFS).

Critères d'éligibilité	• Able to understand and give written informed consent.
	• Must have adequate tumor tissue sample from locally recurrent or metastatic site.
	• Documented evidence of HR+ metastatic breast cancer (mBC) confirmed with the most recently available tumor biopsy from a locally recurrent or metastatic site.
	• Documented evidence of HER2- status.
	• Documented PD by computed tomography (CT) or magnetic resonance imaging during or after the most recent therapy per RECIST v1.1 criteria.
	• Candidate for the first chemotherapy in the locally advanced or metastatic setting.
	• Eligible for capecitabine, nab-paclitaxel, or paclitaxel.
	• Individuals must have one of the following:
	  • Disease progression on at least 2 or more previous lines of endocrine therapy (ET) with or without a targeted therapy in the metastatic setting.
	  • Disease recurrence while on the first 24 months of starting adjuvant ET will be considered a line of therapy; these individuals will only require 1 line of ET in the metastatic setting.
	  • Disease progression within 6 months of starting first-line ET with or without a cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting.
	  • Disease recurrence while on the first 24 months of starting adjuvant ET with CDK 4/6

	inhibitor and if the individual is no longer a candidate for additional ET in the metastatic setting. • Individuals may have received prior targeted therapies, including but not limited to phosphatidylinositol 3-kinase (PI3K) inhibitors (for those with PIK3CA mutations) or mammalian target of rapamycin (mTOR) inhibitors. However, individuals can no longer be candidates for additional endocrine treatment with or without targeted therapies. • Individuals with HIV must be on antiretroviral therapy (ART) and have a well-controlled HIV infection/disease. • Demonstrates adequate organ function. • Male individuals and female individuals of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
Critères d'exclusion	• Progressive disease within 6 months of completing (neo)adjuvant chemotherapy. • Locally advanced metastatic breast cancer (mBC) (Stage IIIc) in individuals who are candidates for curative intent therapy at the time of study enrollment. • Current enrollment in another clinical study or use of any investigational device or drug either within 5 half-lives or 28 days prior to randomization, whichever is longer. • Received any prior treatment (including antibody-drug conjugate (ADC)) containing a chemotherapeutic agent targeting topoisomerase I. • Received any prior treatment with a trophoblast cell-surface antigen 2 (Trop-2)-directed ADC. • Have an active second malignancy. • Have an active serious infection requiring antibiotics. • Have active hepatitis B virus (HBV) or hepatitis C virus (HCV). • Individuals positive for human immunodeficiency virus type 1/2 (HIV-1 or -2) with a history of Kaposi sarcoma and/or Multicentric Castleman Disease. • Have a positive serum pregnancy test or are breastfeeding for individuals who are assigned female at birth.