Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Inavolisib in Combination With Phesgo Versus Placebo in Combination With Phesgo As Maintenance Therapy After First Line Induction Therapy in Participants With PIK3CA-Mutated HER2-Positive Locally Advanced or Metastatic Breast Cancer
Protocole ID	WO44263
ClinicalTrials.gov ID	NCT05894239
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Inavolisib en association avec Phesgo versus placebo en association avec Phesgo
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
Investigateur principal	Dre Catherine Doyle
Coordonnateur	Fanie Bourgault 418-525-4444 poste 82697
Statut	Actif en recrutement
Date d'activation	18-08-2023
But étude	This study will evaluate the efficacy and safety of inavolisib in combination with Phesgo (pertuzumab, trastuzumab, and rHuPH20 injection for subcutaneous use) compared with placebo in combination with Phesgo, as maintenance therapy, after induction therapy in participants with previously untreated HER2-positive advanced breast cancer (ABC).
Critères d'éligibilité	• Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1 • Histologically or cytologically confirmed and documented adenocarcinoma of the breast with metastatic or locally advanced disease not amenable to curative resection • Confirmation of HER2 biomarker eligibility based on valid results from central testing of tumor tissue documenting HER2-positivity • Confirmation of PIK3CA-mutation biomarker eligibility based on valid results from central testing of tumor tissue documenting PIK3CA-mutated tumor status • Disease-free interval from completion of adjuvant or neoadjuvant systemic non-hormonal treatment to recurrence of >= 6 months • LVEF (left ventricular ejection fraction) of at least 50% measured by echocardiogram (ECHO) or multiple-gated acquisition scan (MUGA) • Adequate hematologic and organ function prior to initiation of study treatment

Critères d'exclusion	• Prior treatment in the locally advanced or metastatic setting with any PI3K, AKT, or mTOR inhibitor or any agent whose mechanism of action is to inhibit the PI3K-AKT-mTOR pathway • Any prior systemic non-hormonal anti-cancer therapy for locally advanced or metastatic HER2-positive breast cancer prior to initiation of induction therapy • History or active inflammatory bowel disease • Disease progression within 6 months of receiving any HER2-targeted therapy • Type 2 diabetes requiring ongoing systemic treatment at the time of study entry; or any history of Type 1 diabetes • Clinically significant and active liver disease, including severe liver impairment, viral or other hepatitis, current alcohol abuse, or cirrhosis • Symptomatic active lung disease, including pneumonitis or interstitial lung disease • Any history of leptomeningeal disease or carcinomatous meningitis • Serious infection requiring IV antibiotics within 7 days prior to Day 1 of Cycle 1 • Any concurrent ocular or intraocular condition that, in the opinion of the investigator, would require medical or surgical intervention during the study period to prevent or treat vision loss that might result from that condition • Active inflammatory or infectious conditions in either eye or history of idiopathic or autoimmune-associated uveitis in either eye