Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude de phase II à double insu, contrôlée par placebo du Seribantumab plus Fulvestrant chez des femmes post-ménopausées avec un cancer du sein métastatique qui sont Récepteurs Hormonaux positifs (RH+), Héréguline positif (HRG+) et HER2 négatif (HER2-).
Protocole ID	SHERBOC/MM-121-02-02-10
ClinicalTrials.gov ID	NCT03241810
Type(s) de cancer	Sein
Phase	Phase II
Médicament	Seribantumab plus Fulvestrant
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
Investigateur principal	Dr André Blais
Coordonnateur	Guylaine Julien 418-682-7511 poste 7384
Statut	Fermé
But étude	This study is a multi-center, randomized, double-blind, placebo-controlled, Phase 2 study in postmenopausal women with heregulin positive, hormone receptor positive, HER2 negative metastatic, unresectable breast cancer.
Critères d'éligibilité	To be eligible for participation in the study, patients must meet the following criteria. Patients who are HRG negative do not need to complete screening procedures beyond HRG assessment. • Patients must have histologically or cytologically confirmed ER+ and/or PR+ (with staining of >1% cells) breast cancer. • Patients with confirmed postmenopausal status due to either surgical/natural menopause or ovarian suppression. • Patients must be HER2 negative. • Patient must have at least one lesion amenable to either core needle biopsy or fine needle aspiration. • Patient must have a positive in-situ hybridization (ISH) test for heregulin, as determined by centralized testing of unstained tumor tissue. • Patients that have progressed following at least one but no more than two prior systemic therapies in the locally advanced or metastatic disease setting. • Patients with documented progression of locally advanced or metastatic disease as defined by RECISTv1.1 (Exception: patients with bone-only metastatic disease are eligible if they have at least 2 lytic lesions visible on a CT or MRI and have documented disease progression on prior therapy based on the appearance of new lesions). • Patients with bone-only lesions who have received radiation to those lesions must have documented progression following radiation therapy. • ECOG Performance Score (PS) of 0 or 1. • Patients with adequate bone marrow reserves. • Adequate hepatic function. • Adequate renal function. • Patient has recovered from clinically significant effects of any prior, surgery, radiosurgery, or other antineoplastic therapy. • Patients who have experienced a venous thromboembolic event within 60 days of signing the main consent form should have been treated with anti-coagulants for at least 7 days prior to beginning treatment and for the duration of treatment on this study.

Critères d'exclusion	Patients must meet all the inclusion criteria listed above and none of the following exclusion criteria. • Prior treatment with an anti-ErbB3 antibody. • Prior treatment with a chemotherapy in the locally advanced or metastatic disease setting. • Patients cannot have received prior treatment with fulvestrant or other SERDs in the locally advanced or metastatic setting. • Uncontrolled CNS disease or presence of leptomeningeal disease. • Inflammatory breast cancer. • History of another active malignancy that required systemic therapy in the last 2 years. Patients with prior history of in-situ cancer, basal, or squamous cell skin cancer are eligible. • Patients with an active infection, or unexplained fever > 38.5 C during screening visits or on the first scheduled day of dosing, which in the investigator's opinion might compromise the patients participation in the trial or affect the study outcome. At the discretion of the investigator, patients with tumor fever may be enrolled. • Known hypersensitivity to any of the components of seribantumab, fulvestrant, or who have had hypersensitivity reactions to fully human monoclonal antibodies. • NYHA Class III or IV congestive heart failure. • Patients with a significant history of cardiac disease (i.e. uncontrolled blood pressure, unstable angina, myocardial infarction within 1 year or ventricular arrhythmias requiring medication) are also excluded. • Uncontrolled infection requiring IV antibiotics, antivirals, or antifungals; or active human immunodeficiency virus (HIV) infection, active hepatitis B infection or active hepatitis C infection.