Essai Clinique

Généré le 06 mai 2024 à partir de http://www.geoq.info/fr/pub/essai-clinique-2895-pdf

Titre	Étude de phase III randomisée, à double insu et contrôlée par placébo visant à évaluer l'association de tasélisib et de fulvestrant comparativement à l'association d'un placébo et de fulvestrant chez des femmes post-ménopausées atteintes d'un cancer du sein localement avancé ou métastatique positif aux récepteurs de l'oestrogène et HER2 négatif, dont la maladie récidive ou progresse pendant ou après un traitement par un inhibiteur de l'aromatase.
Protocole ID	G029058 (SANDPIPER)
ClinicalTrials.gov ID	NCT02340221
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	taselisib
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
Investigateur principal	Dre Louise Provencher
Coordonnateur	Nathalie Carmichael 418-682-7511 poste 4551
Statut	Fermé
But étude	This international, multicenter, randomized, double-blinded, placebo-controlled study is designed to compare the efficacy and safety of taselisib + fulvestrant with that of placebo + fulvestrant in postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative, PIK3CA-mutant, unresectable, locally advanced or metastatic breast cancer after recurrence or progression during or after an aromatase inhibitor (AI) therapy. There will be a 2:1 randomization to the taselisib arm versus the placebo arm. Enrollment will be enriched for patients with PIK3CA mutant tumors via central testing. The anticipated duration of the study is approximately 3.5 years.
Critères d'éligibilité	• Postmenopausal women with histologically or cytologically confirmed locally advanced or metastatic estrogen-receptor positive (ER+) breast cancer • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Endocrine therapy (e.g., fulvestrant) is recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study • Radiologic/objective evidence of recurrence or progression to the most recent systemic therapy for breast cancer • Recurrence or progression during or after aromatase inhibitor • Evaluable or measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 • Consent to provide tumor tissue (block or a minimum of 20 slides) from the most recent tumor tissue for PIK3CA-mutation testing; a valid cobas® PIK3CA mutation result by central testing is required • Adequate hematologic and end-organ function within 28 days prior to treatment initiation

Critères d'exclusion	• HER2-positive disease by local laboratory testing (immunohistochemistry [IHC] 3+ staining or in situ hybridization positive) • Prior treatment with fulvestrant • Prior treatment with a PI3K inhibitor, mTOR inhibitor (e.g. everolimus), or AKT inhibitor • Prior anti-cancer therapy within 2 weeks prior to Day 1 of Cycle 1 • Prior radiation therapy within 2 weeks prior to Day 1 of Cycle 1 • All acute treatment-related toxicity must have resolved to Grade • Prior treatment with > 1 cytotoxic chemotherapy regimen for metastatic breast cancer • Concurrent hormone replacement therapy • Known untreated or active central nervous system (CNS) metastases • Type 1 or Type 2 diabetes mellitus requiring anti-hyperglycemic medications • History of inflammatory bowel disease or active bowel inflammation • Clinically significant cardiac or pulmonary dysfunction • Clinically significant history of liver disease, including cirrhosis, current alcohol abuse, or current known active infection with HIV, hepatitis B or C virus