Essai Clinique

Généré le 06 mai 2024 à partir de

Titre	An Open Label Randomized Phase 2 Trial of SAR439859, Versus Endocrine Monotherapy as Per Physician's Choice in Patients With Estrogen Receptor-positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer With Prior Exposure to Hormonal Therapies
Protocole ID	AMEERA-3
ClinicalTrials.gov ID	NCT04059484
Type(s) de cancer	Sein
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	SAR439859
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Cristiano Ferrario
Coordonnateur	Heather Gregory 514-340-8222 poste 24596
Statut	Fermé
But étude	To determine whether SAR439859 per os improves progression free survival (PFS) when compared with a endocrine monotherapy of the choice of the physician, in participants with metastatic or locally advanced breast cancerThe duration of the study for an individual participant will include a period to assess eligibility (screening period) of up to 4 weeks (28 days), a treatment period of at least 1 cycle (28 days of study treatment), and an end of treatment (EOT) visit at least 30 days (or until the participant receive another anticancer therapy, whichever is earlier) following the last administration of study treatment. Study treatment may continue until precluded by unacceptable toxicity, disease progression, death or upon participant's request.
Critères d'éligibilité	• 18 years or older • Histological or cytological diagnosis of adenocarcinoma of the breast. • Locally advanced not amenable to radiation therapy or surgery in a curative intent, and/or metastatic disease. • ER positive status • HER2 negative status • For patients with tumor accessible for paired biopsy at study entry: baseline samples, formalin fixed paraffin embedded (FFPE) archived biopsy samples (within 3 months prior initiation of study treatment) can be used, but preferably fresh biopsies from primary tumor or recurrence or metastasis, will be collected. • Participants must have received no more than 1 prior chemotherapeutic or 1 targeted therapy regimen for advanced/metastatic disease. • Participants must have progressed after at least 6 months of a continuous prior endocrine therapy for advanced breast cancer

Critères d'exclusion	• Eastern Cooperative Oncology Group performance status ≥2. • Medical history or ongoing gastrointestinal disorders potentially affecting the absorption of SAR439859. Participants unable to swallow normally and to take capsules. • Participant with any other cancer. Adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer or any other cancer from which the participant has been disease free for >3 years are allowed. • Severe uncontrolled systemic disease at screening . • Participants with known brain metastases that are untreated, symptomatic or require therapy to control symptoms. • Prior treatment with mammalian target of rapamycin inhibitors or any other selective estrogen receptor degrader (SERD) compound, except fulvestrant if stopped for at least3 months before randomization. • Treatment with drugs that have the potential to inhibit UGT less than 2 weeks before randomization . • Treatment with strong or moderate CYP3A/CYP2C8 inducers within 2 weeks before randomization. • Ongoing treatment with drugs that are substrate of P-glycoprotein (P gp) (dabigatran, digoxin, fexofenadine). • Treatment with anticancer agents (including investigational drugs) less than 3 weeks before randomization. • Inadequate hematological, coagulation, renal and liver functions. • The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.