Essai Clinique

Généré le 24 avr. 2024 à partir de

Titre	Étude de phase III à répartition aléatoire, multicentrique et à double insu portant sur l'association amcénestrant (SAR439859) plus palbociclib par rapport à l'association létrozole plus palbociclib pour le traitement des patientes atteintes d'un cancer du sein ER(+), HER2(-) n'ayant pas reçu de traitement anticancéreux systémique antérieur pour une maladie avancée
Protocole ID	AMEERA-5 (EFC15935)
ClinicalTrials.gov ID	NCT04478266
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Amcenestrant + Palbociclib versus Letrozole + Palbociclib
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jamil Asselah
Coordonnateur	Neera Sriskandarajah 514-934-1934 poste 36686
Statut	Fermé
But étude	To determine whether Amcenestrant (SAR439859) in combination with palbociclib improves progression free survival (PFS) when compared with letrozole in combination with palbociclib in participants with ER+, HER2- advanced breast cancer who have not received any prior systemic anticancer therapies for advanced disease.
Critères d'éligibilité	• Adult participants with loco-regional recurrent or metastatic disease not amenable to curative treatment • Confirmed diagnosis of ER+/HER2- breast cancer • No prior systemic treatment for loco-regional recurrent or metastatic disease • Measurable disease evaluable per Response Evaluation Criterion in Solid Tumors (RECIST) v.1.1 or non-measurable bone-only disease • Eastern Cooperative Oncology Group (ECOG) performance status 0-2 • Participants should be willing to provide tumor tissue • Capable of giving informed consent
Critères d'exclusion	• Known active brain metastases • Prior neo (adjuvant) treatment with any selective estrogen receptor degrader (SERD) • Inadequate organ and marrow function • Disease recurrence while on, or within 12 months of completion of (neo)adjuvant endocrine therapy • Pregnant, breastfeeding, or woman of child bearing potential unwilling to use recommended contraception methods • Male participants who disagree to follow contraception • Participants with advanced, symptomatic visceral spread, that are at risk of life-threatening complications in the short term • Participants with significant concomitant illness

The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.