Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	A Phase III, Double-blind, Randomised Study to Assess Switching to AZD9833 (a Next Generation, Oral SERD) + CDK4/6 Inhibitor (Palbociclib or Abemaciclib) vs Continuing Aromatase Inhibitor (Letrozole or Anastrozole)+ CDK4/6 Inhibitor in HR+/HER2-MBC Patients With Detectable ESR1Mutation Without Disease Progression During 1L Treatment With Aromatase Inhibitor+ CDK4/6 Inhibitor- A ctDNA Guided Early Switch Study
Protocole ID	SERENA-6
ClinicalTrials.gov ID	NCT04964934
Type(s) de cancer	Sein
Phase	Phase III
Stade	Métastatique
Type étude	Clinique
Médicament	AZD9833 + inhibiteur de CDK4/6 (palbociclib ou abémaciclib) vs inhibiteur de l'aromatase (létrozole ou anastrozole) + inhibiteur CDK4/6
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
Investigateur principal	Dre Catherine Doyle
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Statut	Actif en recrutement
But étude	The study is intended to show superiority of AZD9833 in combination with CDK4/6 inhibitor (palbociclib or abemaciclib) versus aromatase inhibitors (anastrozole or letrozole) in combination with CDK4/6 inhibitor in patients with hormone receptor-positive (HR-positive), human epidermal growth factor receptor 2-negative (HER2-negative) metastatic breast cancer with detectable ESR1 mutation
Critères d'éligibilité	• Proven diagnosis of adenocarcinoma of the breast with evidence of locoregionally recurrent or metastatic disease not amenable to resection or radiation therapy with curative intent. • Documentation of histologically confirmed diagnosis of estrogen receptor positive (ER+) /HER2- breast cancer based on local laboratory results. • Currently on AI (letrozole or anastrozole) + CDK4/6 inhibitor (palbociclib or abemaciclib) ± LHRH as the initial endocrine based treatment for advanced disease • Eastern Cooperative Oncology Group performance status of 0 or 1. • ESR1m positive detected by central testing of ctDNA • Willingness and ability to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures. • Adequate organ and marrow function
Critères d'exclusion	• Advanced, symptomatic, visceral spread, that are at risk of life-threatening complications in the short term. • Known active uncontrolled or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease. • Any evidence of severe or uncontrolled systemic diseases which, in the investigator's opinion, makes it undesirable for the participant to participate in the study or that would jeopardize compliance with the protocol.

- Patient with known or family history of severe heart disease
- Previous treatment with AZD9833, investigational SERDs or fulvestrant.
- Currently pregnant (confirmed with positive pregnancy test) or breastfeeding.
- Persistent non-haematological toxicities (CTCAE Grade > 2) caused by CDK4/6 inhibitor and/or AI treatment.