Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Randomised, Multicentre, Double-Blind, Phase III Study of AZD9833 (an Oral SERD) Plus Palbociclib Versus Anastrozole Plus Palbociclib for the Treatment of Patients With Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer Who Have Not Received Any Systemic Treatment for Advanced Disease
Protocole ID	SERENA-4:
ClinicalTrials.gov ID	NCT04711252
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	AZD9833 + Palbociclib versus Anastrozole + Palbociclib
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	Dima Obari 514-340-8222 poste 24596
Statut	Actif en recrutement
But étude	The study is intended to show superiority of AZD9833 in combination with palbociclib (a CDK4/6 inhibitor) versus anastrozole (an aromatase inhibitor) and palbociclib as the initial treatment of patients with hormone receptor-positive (ER-positive), human epidermal growth factor 2-negative (HER2-negative) advanced/metastatic breast cancer.
Critères d'éligibilité	• Pre-/peri-menopausal women or men can be enrolled if amenable to be treated with concomitant, approved LHRH agonists for the duration of the study treatment. • De novo Stage 4 disease, or recurrence from early stage disease after standard adjuvant endocrine therapy meeting either one of the following criteria: 1. Received at least 24 months of AI treatment as part of their adjuvant therapy and at least 12 months have elapsed since the patient's last dose of adjuvant AI therapy without disease progression on treatment 2. Received at least 24 months of tamoxifen treatment as part of their adjuvant endocrine therapy • Histologically or cytologically documented diagnosis of ER+, HER2-negative breast cancer based on local laboratory results. • Previously untreated with any systemic anti-cancer therapy for their locoregionally recurrent or metastatic ER+ disease. • Measurable disease as defined per RECIST v.1.1 OR at least one lytic or mixed (lytic + sclerotic) bone lesion that can be assessed by CT or MRI. • Eastern Cooperative Oncology Group performance status of 0 or 1. • Adequate organ and marrow function. • Willingness and ability to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.

Critères d'exclusion	• Previous neoadjuvant or adjuvant treatment with an AI treatment +/- CDK4/6 inhibitor with disease recurrence while on or within 12 months of completing treatment. • Previous treatment with AZD9833. • Participation in another clinical study with a study treatment or investigational medicinal device administered in the last 4 weeks prior to randomization or concurrent enrollment in another clinical study, unless it is an observational (non-interventional) clinical study or during the follow-up period of an interventional study. • 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 clinically important and symptomatic heart disease . • Currently pregnant (confirmed with positive pregnancy test) or breast-feeding. • As judged by the investigator, any evidence of diseases (such as severe or uncontrolled systemic diseases, renal transplant and active bleeding 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. • Any concurrent anti-cancer treatment.