Essai Clinique

Généré le 27 avr. 2025 à partir de

Titre	A Phase III Randomized, Open-Label Study Evaluating Efficacy and Safety of Giredestrant Compared With Fulvestrant, Both Combined With a CDK4/6 Inhibitor, in Patients With Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer With Resistance to Prior Adjuvant Endocrine Therapy
Protocole ID	pionERA Breast Cancer
ClinicalTrials.gov ID	NCT06065748
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Giredestrant comparé au fulvestrant
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
Investigateur principal	Dre Julie Lemieux
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Statut	Actif en recrutement
But étude	This is a Phase III, randomized, open-label multicenter study that will evaluate the efficacy and safety of giredestrant compared with fulvestrant, both in combination with the investigator's choice of a CDK4/6 inhibitor (palbociclib, ribociclib or abemaciclib), in participants with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer who have developed resistance to adjuvant endocrine therapy.
Critères d'éligibilité	• Locally advanced or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent • Documented estrogen receptor-positive (ER+), HER2-negative (HER2-) tumor assessed locally on the most recent tumor biopsy (or archived tumor sample) • Confirmed ESR1 mutation status (ESR1m vs. ESR1nmd) in baseline circulating tumor DNA (ctDNA) through central laboratory testing • Resistance to prior adjuvant endocrine therapy (ET). Prior use of neo/adjuvant CDK4/6i is allowed. • No prior systemic anti-cancer therapy for advanced disease • Measurable disease as defined per RECIST v.1.1 or non-measurable bone-only disease • Eastern Cooperative Oncology Group Performance Status (ECOG PS) 0-1 • For pre/perimenopausal women and for men: treatment with LHRH agonist therapy (as per local guidelines) for the duration of study treatment is required
Critères d'exclusion	• Prior systemic therapy (e.g., prior chemotherapy, immunotherapy, or biologic therapy) for locally advanced unresectable or metastatic breast cancer • Prior treatment with another SERD (e.g., fulvestrant, oral SERDs) or novel ER-targeting agents • Advanced, symptomatic, visceral spread that is at risk of life-threatening complications in the short term • Active cardiac disease or history of cardiac dysfunction • Clinically significant history of liver disease