


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	<a href="https://clinicaltrials.gov/ct2/show/study/NCT06065748">NCT06065748</a>
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Giredestrant comparé au fulvestrant
Institution	CIUSSS DU SAGUENAY – LAC-SAINT-JEAN  HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
Investigateur principal	Dr José Luiz Miranda Guimaraes
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Statut	Actif en recrutement
Date d'activation	15-11-2023
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	<ul style="list-style-type: none"><li>• Locally advanced or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent</li><li>• Documented estrogen receptor-positive (ER+), HER2-negative (HER2-) tumor assessed locally on the most recent tumor biopsy (or archived tumor sample)</li><li>• Confirmed ESR1 mutation status (ESR1m vs. ESR1nmd) in baseline circulating tumor DNA (ctDNA) through central laboratory testing</li><li>• Resistance to prior adjuvant endocrine therapy (ET). Prior use of neo/adjuvant CDK4/6i is allowed.</li><li>• No prior systemic anti-cancer therapy for advanced disease</li><li>• Measurable disease as defined per RECIST v.1.1 or non-measurable bone-only disease</li><li>• Eastern Cooperative Oncology Group Performance Status (ECOG PS) 0-1</li><li>• For pre/perimenopausal women and for men: treatment with LHRH agonist therapy (as per local guidelines) for the duration of study treatment is required</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• Prior systemic therapy (e.g., prior chemotherapy, immunotherapy, or biologic therapy) for locally advanced unresectable or metastatic breast cancer</li><li>• Prior treatment with another SERD (e.g., fulvestrant, oral SERDs) or novel ER-targeting agents</li><li>• Advanced, symptomatic, visceral spread that is at risk of life-threatening complications in the short term</li><li>• Active cardiac disease or history of cardiac dysfunction</li><li>• Clinically significant history of liver disease</li></ul>

