Essai Clinique

Généré le 25 avr. 2025 à partir de

Titre	A phase 3, randomized, open-label, multicenter trial of ARV-471 (PF-07850327) vs fulvestrant in participants with estrogen receptor-positive, her2-negative advanced breast cancer whose disease progressed after prior endocrine based treatment for advanced disease
Protocole ID	VERITAC-2
ClinicalTrials.gov ID	NCT05654623
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	ARV-471 (PF-07850327) versus fulvestrant
Institution	CISSS DES LAURENTIDES HOPITAL DE SAINT-JEROME 290 Rue de Montigny, Saint-Jérôme, QC, J7Z 5T3
Ville	
Investigateur principal	Dr Ghislain Cournoyer
Coordonnateur	Yanick Sardin Laframboise 450-431-1020 poste 23429
Statut	Fermé
But étude	A study to learn about a new medicine called ARV-471 (PF-07850327) in people who have advanced metastatic breast cancer.
Critères d'éligibilité	• Adult participants with loco-regional recurrent or metastatic breast disease not amenable to surgical resection or radiation therapy • Confirmed diagnosis of ER+/HER2- breast cancer • Prior therapies for locoregional recurrent or metastatic disease must fulfill all the following criteria: • One line of CDK4/6 inhibitor therapy in combination with endocrine therapy. Only one line of CDK4/6 inhibitor is allowed in any setting. • ≤ 1 endocrine therapy in addition to CDK4/6 inhibitor with ET • Most recent endocrine treatment duration must have been given for ≥6 months prior to disease progression. This may be the endocrine treatment component of the CDK4/6 inhibitor line of therapy. • Radiological progression during or after the last line of therapy. • 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 0-1 • Participants should be willing to provide blood and tumor tissue
Critères d'exclusion	• Participants with advanced, symptomatic visceral spread, that are at risk of life-threatening complications in the short term • Prior treatment with: • ARV-471, fulvestrant, elacestrant, mTOR, PI3K, AKT pathway inhibitors, PARP inhibitor for any setting • other investigational agents (including novel endocrine therapy any SERDs, SERCAs, CERANs) for any setting • prior chemotherapy for advanced/metastatic disease • Inadequate liver, kidney and bone marrow function • Active brain metastases • Participants with significant concomitant illness