Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	An interventional, open-label, randomized, multicenter phase 3 study of PF-07220060 plus fulvestrant compared to investigator's choice of therapy in participants over 18 years of age with hormone receptor-positive, HER2-negative advanced/metastatic breast cancer whose disease progressed after prior CDK 4/6 inhibitor-based therapy
Protocole ID	C4391022
ClinicalTrials.gov ID	NCT06105632
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	PF-07220060 avec fulvestrant
Institution	CIUSSS DU SAGUENAY – LAC-SAINT-JEAN H HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
Investigateur principal	Dr José Luiz Miranda Guimaraes
Coordonnateur	Sabrina Côté 418-541-1000 poste 3065
Statut	Actif en recrutement
Date d'activation	17-05-2024
But étude	The purpose of this study is to learn about the safety and how effective the study medicine (PF-07220060) plus fulvestrant is compared to the study doctor's choice of treatment in people with advanced or metastatic breast cancer. Advanced cancer is the one that is unlikely to be cured or taken care of with treatment. Metastatic cancer is the one that has spread to other parts of the body.This study is seeking female and male participants who: • are 18 years of age or older; • are hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative; • have advanced or metastatic breast cancer after taking other treatments before this study; • have not taken or need to take medications that are not allowed by the study protocol; • do not have any medical or mental conditions that may increase the risk of study participation. Half of the participants will take PF-07220060 two times daily by mouth along with fulvestrant. Fulvestrant will be given as a shot into the muscle. The other half will take the study doctor's choice of treatment which can either be: • Fulvestrant alone taken as shot into the muscle. • Everolimus along with exemestane taken once daily by mouth. This study will compare the experiences of participants receiving the study medicine plus fulvestrant to those who are receiving the study doctor's choice of treatment. This will help decide if the study medicine is safe and effectiveParticipants will receive study treatment and/or will be in the study until: • imaging scans (such as an MRI and/or CT) show that their cancer is getting worse. • the study doctor thinks the participant is no longer benefitting from the study medicine. • has side effects that become too severe. A side effect is a reaction (expected or unexpected) to a medicine or treatment you take. • the participant chooses to stop taking part.

Critères d'éligibilité	• Histological confirmation of breast cancer with evidence of locally advanced or metastatic disease, which is not amenable to surgical resection or radiation therapy with curative intent. • Documented estrogen receptor (ER) and/or progesterone receptor (PR)- positive tumor • Documented HER2-negative tumor • Able to provide a sufficient amount of representative formalin fixed, paraffin embedded (FFPE) tumor tissue specimen. • Must have received CDK4/6i plus NSAI defined per study protocol. There must be documented PD during or after CDK4/6i treatment. • Measurable disease or non-measurable bone only disease as defined by RECIST version 1.1. • Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) ≤2.
Critères d'exclusion	• Any medical or psychiatric condition that may increase the risk of study participation or make the participant inappropriate for the study. • In visceral crisis at risk of immediately life-threatening complications in the short term. • Known active uncontrolled or symptomatic central nervous system metastases, carcinomatous meningitis, or leptomeningeal disease. • Prior treatment with any of the following: • Everolimus or investigational anti-cancer agents in any setting • Prior chemotherapy in the advanced setting • Radiation within 2 weeks of randomization • Current use or anticipated need for any prohibited food, supplements or concomitant medication(s) (ie, other anti-cancer therapies, other endocrine therapies, growth factors, chronic systemic corticosteroids, strong cytochrome P450 3A4/5 [CYP3A4/5] or uridine 5' diphosphate-glucuronosyltransferase 2B7 [UGT2B7] inhibitors and inducers, direct oral anticoagulants, proton pump inhibitors). • Inadequate renal function, hepatic dysfunction, or hematologic abnormalities.