Essai Clinique

Généré le 21 mai 2024 à partir de

Titre	An interventional safety and efficacy phase 1b/2, open-label umbrella study to investigate tolerability, pk, and antitumor activity of ARV-471 (PF-07850327), an oral proteolysis targeting chimera, in combination with other anticancer treatments in participants aged 18 years and over with ER+ advanced or metastatic breast cancer, sub-study B (ARV-471 in combination with ribociclib)
Protocole ID	TACTIVE-U
ClinicalTrials.gov ID	NCT05573555
Type(s) de cancer	Sein
Phase	Phase I-II
Type étude	Clinique
Médicament	ARV-471 (PF-07850327)
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
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Statut	Actif en recrutement
Date d'activation	01-08-2023
But étude	The purpose of this clinical trial is to learn about the safety and effects of the study medicine (called ARV-471) when given together with other medicines for the potential treatment of advanced or metastatic breast cancerThis study is seeking participants who have breast cancer that: • is advanced, may have spread to other organs (metastatic) and cannot be fully treated by surgery or radiation therapy • is sensitive to hormonal therapy (it is called estrogen receptor positive); and • is no longer responding to previous treatments This study is divided into separate sub-studies. For Sub-Study B: All participants will receive ARV-471 and a medicine called ribociclib. ARV-471 and ribociclib will be given at the same time by mouth, at home, 1 time a dayThe experiences of people receiving the study medicine will be examined. This will help determine if the study medicine is safe and effective.Participants will continue to take ARV-471 and ribociclib until their cancer is no longer responding, or side effects become too severe. They will have visits at the study clinic about every 4 weeks.
Critères d'éligibilité	• histological or cytological diagnosis of ER+ and HER2- advanced/metastatic breast cancer that is not amendable to surgical resection with curative intent (≥1% ER+ stained cells on the most recent tumor biopsy). • prior anticancer therapies: up to 2 lines of prior therapies for advanced/metastatic disease; 1 line of any CDK4/6 inhibitor-based regimen is required (in any setting eg adjuvant, metastatic) • at least 1 measurable lesion as defined by RECIST v1.1. • ECOG PS ≤1.

Critères d'exclusion	• visceral crisis at risk of life-threatening complications in the short term • known history of drug-induced pneumonitis or other significant symptomatic deterioration of lung functions. • newly diagnosed brain metastases, or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease. Participants with a history of CNS metastases or cord compression are eligible if they have been definitively treated, clinically stable and discontinued anti-seizure medications and corticosteroids for at least 14 days prior to enrollment in the of study. • history of any other tumor malignancies within the past 3 years, except for the following: (1) adequately treated basal or squamous cell carcinoma of the skin; (2) curatively treated in situ carcinoma of the cervix. • inflammatory breast cancer • impaired cardiovascular function or clinically significant cardiovascular diseases • concurrent administration of medications, food, or herb supplements that are strong inhibitors and strong/moderate inducers of CYP3A and drugs known to predispose to Torsade de Pointes or QT interval prolongation. • renal impairment, not adequate liver function and/or bone marrow function • known active infection