




Essai Clinique

Généré le 04 mai 2025 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  HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
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Statut	Actif en recrutement
Date d'activation	01-08-2023
But étude	<p>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 cancer. This study is seeking participants who have breast cancer that:</p> <ul style="list-style-type: none">• 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 <p>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 day. The 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.</p>
Critères d'éligibilité	<ul style="list-style-type: none">• 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