Essai Clinique

Généré le 18 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 a (arv-471 in combination with abemaciclib)
Protocole ID	TACTIVE-U
ClinicalTrials.gov ID	NCT05548127
Type(s) de cancer	Sein
Phase	Phase I-II
Type étude	Clinique
Médicament	ARV-471 et abémaciclib
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dre Jennifer Friedmann
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Statut	Actif en recrutement
Date d'activation	14-02-2024
But étude	C4891006 is a sub-study from the Umbrella platform, TACTIVE-U, comprising multiple sub-studies that independently evaluate ARV-471 in participants with Estrogen Receptor Positive (ER+) Advanced or Metastatic Breast Cancer (A/MBC). ARV-471 will act as the backbone therapy given in combination with other anticancer agents thought to have clinical relevance in ER+ breast cancer.
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 (independent of the setting eg, adjuvant or advanced/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 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