Essai Clinique

Généré le 21 mai 2025 à partir de

Titre	Étude de phase 3, ouverte, randomisée, comparant le gédatolisib associé au fulvestrant et avec ou sans palbociclib aux traitements standard chez des patientes atteintes d'un cancer du sein avancé HR-positif, HER2-négatif précédemment traitées avec un inhibiteur CDK4/6 en association avec traitement par inhibiteur non stéroïdien de l'aromatase
Protocole ID	VIKTORIA-1
ClinicalTrials.gov ID	NCT05501886
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Gédatolisib associé au fulvestrant avec ou sans palbociclib comparé aux traitements standard
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Danielle Charpentier
Coordonnateur	Ana Lydia Tkalec 514-890-8000 poste 14186
Statut	Actif en recrutement
But étude	This is a Phase 3, open-label, randomized, clinical trial evaluating the efficacy and safety of gedatolisib plus fulvestrant with or without palbociclib for the treatment of patients with locally advanced or metastatic HR+/HER2- breast cancer following progression on or after CDK4/6 and aromatase inhibitor therapy.
Critères d'éligibilité	• Histologically or cytologically confirmed diagnosis of metastatic or locally advanced breast cancer Adult females, pre- and/or post-menopausal, and adult males. Pre-menopausal (and peri-menopausal) women can be enrolled if amenable to treatment with an LHRH agonist. Patients are to have commenced concomitant treatment with LHRH agonist prior to or on Cycle 1, Day 1 and must be willing to continue on it for the duration of the study. • Negative pregnancy test for women of childbearing potential. Female subjects of childbearing potential must use an effective and/or acceptable contraceptive method from screening until 1 year after the last dose of study treatment • Confirmed diagnosis of estrogen receptor positive and/or progesterone receptor positive, as per American Society of Clinical Oncology/College of American Pathologists (ASCO-CAP) guidelines (2020), based on most recent tumor biopsy utilizing an assay consistent with local standards • Documented HER2 immunohistochemistry (IHC) negative as per ASCO-CAP 2018 guidance • Adequate archival or fresh tumor tissue for the analysis of PIK3CA mutational status • Subject must have documentation of radiological disease progression on or after the last prior treatment and also have radiologically evaluable disease (measurable and/or non-measurable) according to RECIST v1.1, per local assessment. Subjects with bone only disease must have lytic or mixed lytic/blastic lesions that can be accurately assessed; bone only blastic lesions with no soft tissue component is not allowed. • Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 • Life expectancy of at least 3 months • Progressed during or after CDK4/6 inhibitor combination treatment with non-steroidal aromatase inhibitor (AI) • Adequate bone marrow, hepatic, renal and coagulation function

Critères d'exclusion	• History of malignancies other than adequately treated non-melanoma skin cancer, curatively treated in situ cancer of the cervix, or other solid tumors curatively treated with no evidence of disease for ≥3 years
	• Prior treatment with a phosphoinositide 3-kinase (PI3K) inhibitor, a protein kinase B (Akt) inhibitor, or a mechanistic target of rapamycin (mTOR) inhibitor
	• Prior treatment with chemotherapy and antibody drug conjugates for advanced disease is not permitted (prior adjuvant or neoadjuvant chemotherapy is permitted)
	• More than 2 lines of prior endocrine therapy treatment
	• Bone only disease that is only blastic with no soft tissue component
	• Subjects with type 1 diabetes or uncontrolled type 2 diabetes
	• Known and untreated, or active, brain or leptomeningeal metastases a. Subjects with previously treated central nervous system (CNS) metastases may be enrolled in the study if they meet the following criteria: do not require supportive therapy with steroids; do not have seizures and do not exhibit uncontrolled neurological symptoms; stable disease confirmed by radiographic assessment within at least 4 weeks prior to enrollment
	• Patients with advanced, symptomatic, visceral spread that are at risk of life-threatening complication in the short-term
	• History of clinically significant cardiovascular abnormalities such as: Congestive heart failure (New York Heart Association (NYHA) classification ≥ II within 6 months of study entry
	  • Myocardial infarction within 12 months of study entry
	  • History of any uncontrolled (or untreated) clinically significant cardiac arrhythmias, (e.g., ventricular tachycardia), complete left bundle branch block, high grade AV block (e.g., bifascicular block, Mobitz type II and third degree AV block), supraventricular, nodal arrhythmias, or conduction abnormality in the previous 12 months
	  • Uncontrolled hypertension defined by systolic blood pressure (SBP) ≥160 mmHg and/or diastolic blood pressure (DBP) ≥100 mmHg, with or without antihypertensive medication (initiation or adjustment of antihypertensive medication[s] is allowed prior to screening)
	  • Long QT syndrome, family history of idiopathic sudden death or congenital long QT syndrome, or any of the following:
	  • i. Risk factors for Torsades de Pointes (TdP) including uncorrected hypokalemia or hypomagnesemia, or history of clinically significant/symptomatic bradycardia
	  • ii. On screening, inability to determine the corrected QT interval using Fridericia's formula (QTcF) on the ECG (i.e., unreadable or not interpretable) or QTcF >480 msec (determined by mean of triplicate ECGs at screening)
	• Known hypersensitivity to the study drugs or their components
	• Pregnant or breast-feeding women
	• Concurrent participation in another interventional clinical trial
	  • Subjects must agree not to participate in another clinical trial (other than observational) at any time during participation in VIKTORIA-1.