Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude de phase III, à double insu, à répartition aléatoire et contrôlée par placebo, évaluant l'efficacité et l'innocuité du GDC-0077 en association avec le palbociclib et le fulvestrant par rapport à un placebo associé au palbociclib et au fulvestrant chez des patientes atteintes d'un cancer du sein localement avancé ou métastatique à mutation PIK3CA, positif pour les récepteurs hormonaux et négatif pour le récepteur HER2
Protocole ID	WO41554
ClinicalTrials.gov ID	NCT04191499
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	GDC-0077 + Palbociclib et Fulvestrant vs Placebo + Palbociclib et Fulvestrant
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	Dr Cristiano Ferrario
Coordonnateur	Gelareh Arzani 514-340-8222
Statut	Actif en recrutement
But étude	This study will evaluate the efficacy, safety, and pharmacokinetics of GDC-0077 in combination with palbociclib and fulvestrant compared with placebo plus palbociclib and fulvestrant in patients with PIK3CA-mutant, hormone receptor (HR)-positive, HER2-negative locally advanced or metastatic breast cancer whose disease progressed during treatment or within 12 months of completing adjuvant endocrine therapy and who have not received prior systemic therapy for metastatic disease.
Critères d'éligibilité	• Confirmed diagnosis of HR+/HER2- breast cancer • Metastatic or locally advanced disease not amenable to curative therapy • Progression of disease during adjuvant endocrine treatment or within 12 months of completing adjuvant endocrine therapy with an aromatase inhibitor or tamoxifen • Receiving LHRH agonist therapy for at least 2 weeks prior to Day 1 of Cycle 1 if pre/peri-menopausal • Confirmation of biomarker eligibility (detection of specified mutation(s) of PIK3CA via specified test) • Consent to provide fresh or archival tumor tissue specimen • Measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1; "bone-only" disease, even if considered measurable, is not eligible • Eastern Cooperative Oncology Group Performance Status of 0 or 1 • Life expectancy of > 6 months • Adequate hematologic and organ function within 14 days prior to initiation of study treatment

Critères d'exclusion	• Metaplastic breast cancer • Any history of leptomeningeal disease or carcinomatous meningitis • Any prior systemic therapy for metastatic breast cancer • Prior treatment with fulvestrant or any selective estrogen-receptor degrader • Prior treatment with any PI3K, AKT, or mTOR inhibitor, or any agent whose mechanism of action is to inhibit the PI3K-AKT-mTOR pathway • Type 2 diabetes requiring ongoing systemic treatment at the time of study entry; or any history of Type 1 diabetes • Known and untreated, or active CNS metastases. Patients with a history of treated CNS metastases are eligible • Active inflammatory or infectious conditions in either eye, or any eye conditions expected to require surgery during the study treatment period • Symptomatic active lung disease, or requiring daily supplemental oxygen • History of inflammatory bowel disease or active bowel inflammation • Anti-cancer therapy within 2 weeks before study entry • Investigational drug(s) within 4 weeks before randomization • Prior radiotherapy to >= 25% of bone marrow, or hematopoietic stem cell or bone marrow transplantation • Chronic corticosteroid therapy or immunosuppressants • Pregnant, lactating, or breastfeeding, or intending to become pregnant during the study or within 60 days after the final dose of study treatment • Major surgical procedure, or significant traumatic injury, within 28 days prior to Day 1 of Cycle 1