Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Phase III, Multicenter, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Inavolisib Plus Fulvestrant Versus Alpelisib Plus Fulvestrant in Patients With Hormone Receptor-Positive, HER2-Negative, PIK3CA Mutated, Locally Advanced or Metastatic Breast Cancer Who Progressed During or After CDK4/6 Inhibitor and Endocrine Combination Therapy
Protocole ID	INAVO121
ClinicalTrials.gov ID	NCT05646862
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Inavolisib + Fulvestrant versus Alpelisib + Fulvestrant
Institution	CIUSSS DU NORD-DE-L'ILE-DE-MONTREAL H HOPITAL DU SACRE-COEUR-DE-MONTREAL 5400 boul. Gouin Ouest, Montréal, QC, H4J1C5
Ville	
Investigateur principal	Dre Isabelle Gingras
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Statut	Actif en recrutement
Date d'activation	26-07-2023
But étude	This is a Phase III, multicenter, randomized, open-label, global study designed to evaluate the efficacy and safety of inavolisib plus fulvestrant compared with alpelisib plus fulvestrant in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2) -negative, PIK3CA-mutated, locally advanced (LA) or metastatic breast cancer (mBC), who progressed during or after cyclin dependent kinase 4/6i (CDK4/6i)-based therapy.
Critères d'éligibilité	• If pre/perimenopausal women and men treatment with luteinizing hormone-releasing hormone (LHRH) agonist therapy beginning at least 2 weeks prior to Day 1 of Cycle 1 • Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to surgical or radiation therapy with curative intent • Documented HR +/ HER2- tumor according to American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines • Confirmation of biomarker eligibility: detection of specified mutation(s) of PIK3CA via specified test • Disease progression after or during treatment with a combination of CDK4/6i and endocrine therapy: <= 2 prior lines of systemic therapy in mBC setting; CDK4/6i based therapy does not need to be the last one received prior study entry; one line of chemotherapy in mBC setting allowed • Measurable or evaluable disease per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) • Participants for whom endocrine-based therapy is recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study, as per national or local treatment guidelines • Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2

	• Life expectancy of > 6 months • Adequate hematologic and organ function prior to initiation of study treatment
Critères d'exclusion	• Metaplastic breast cancer • Prior treatment in locally advanced or metastatic setting with any PI3K, AKT, or mTOR inhibitor or any agent whose mechanism of action is to inhibit the PI3K/-AKT/-mTOR pathway • Participant who relapsed with documented evidence of progression > 12 months from completion of adjuvant CDK4/6i based therapy with no treatment for metastatic disease • Pregnant, lactating, or breastfeeding, or intending to become pregnant during the study or at least 60 days after the final dose of study treatment • Type 2 diabetes requiring ongoing systemic treatment at the time of study entry; or any history of Type 1 diabetes • Inability or unwillingness to swallow pills • Malabsorption syndrome or other condition that would interfere with enteral absorption • Any history of leptomeningeal disease or carcinomatous meningitis • Known and untreated, or active central nervous system (CNS) metastases. Participants with a history of treated CNS metastases are eligible if they meet specific certain criteria • Known active, systemic infection at study enrollment, or any major episode of infection requiring treatment with intravenous antibiotics or hospitalization within 7 days prior to Day 1 of Cycle 1 • Any concurrent ocular or intraocular condition that, in the opinion of the investigator, would require medical or surgical intervention during the study period to prevent or treat vision loss that might result from that condition • Active inflammatory or infectious conditions in either eye or history of idiopathic or autoimmune-associated uveitis in either eye • Requirement for daily supplemental oxygen • Symptomatic active lung disease, including pneumonitis • History of or active inflammatory bowel disease • Any active bowel inflammation • Clinically significant and active liver disease, including severe liver impairment, viral or other hepatitis, current alcohol abuse, or cirrhosis • Participants with known human immunodeficiency virus infection that meet specific criteria • Investigational drug(s) within 4 weeks before randomization or within 5 half-lives of the investigational drug(s), whichever is longer • History of other malignancy within 5 years prior to screening, except for cancers with very low risk of recurrence • Chronic therapy of >= 10 mg of prednisone per day or an equivalent dose of other anti-inflammatory corticosteroids or immunosuppressants for a chronic disease • Allergy or hypersensitivity to components or excipients of the inavolisib, fulvestrant, or alpelisib formulations • History of severe cutaneous reactions like Stevens-Johnson Syndrome, Erythema Multiforme, Toxic Epidermal Necrolysis, or Drug Reaction with Eosinphilia and Systemic Symptoms • Active ongoing osteonecrosis of the jaw