Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Une étude de phase III randomisée, contrôlée par placebo et à double insu de fulvestrant et d'ipatasertib en tant que traitement du cancer du sein avancé négatif pour le récepteur 2 du facteur de croissance épidermique humain et positif pour les récepteurs des œstrogènes, après la progression de la maladie sous traitement de première ligne par un inhibiteur de la kinase dépendante des cyclines 4 et 6 en association avec un inhibiteur de l'aromatase
Protocole ID	MA.40 (Finer)
ClinicalTrials.gov ID	NCT04650581
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Fulvestrant and Ipatasertib
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	
Investigateur principal	Dre Catherine Prady
Coordonnateur	Marie-Ève Yelle 450-466-5000 poste 3281
Statut	Actif en recrutement
But étude	Patients enrolled in this study will receive either Ipatasertib plus Fulvestrant or placebo (a substance that looks like the study drug but does not have any active or medicinal ingredient) plus Fulvestant. The study will provide information about the ability of Ipatasertib plus Fulvestrant to control the cancer, the side effects and safety of the treatment, how patients feel while taking the treatment and associated costs.

Critères d'éligibilité	• Histologically and/or cytologically confirmed ER positive, HER-2 negative breast cancer
	• Female patients must be post-menopausal; female patients who are pre-menopausal must have ovarian suppression using LHRH agonist while on study
	• Clinical and/or radiographic progression during treatment with or within 28 days after discontinuation of first line of treatment with a CDK 4/6 inhibitor and an aromatase inhibitor (AI) for advanced/metastatic disease
	• Evidence of clinically and/or radiologically documented disease
	• ≥ 18 years of age
	• ECOG performance status of 0 or 1
	• No concurrent anti-cancer therapy and must satisfy the following criteria for previous therapy
	  • Must not have received more than one prior line of treatment with a CDK 4/6 inhibitor and an AI in the advanced disease setting.
	  • Treatment with CDK 4/6 inhibitor and AI must have been the most recent treatment prior to registration for this study
	• Adequate hematology and organ function, in the absence of growth factors
	  • Absolute neutrophils > 1.5 x 10^9/L
	  • Platelets ≥ 100 x 10^9/L
	  • Hemoglobin > 90 g/L
	  • Total Bilirubin ≤ 1.5 x ULN (upper limit of normal) or ≤ 3 x ULN if confirmed Gilbert's Syndrome
	  • ALT and AST ≤ 2.5 x ULN (or ≤ 5.0 x ULN if liver or bone metastasis)
	  • Alkaline phosphatase ≤ 2.0 x ULN (or ≤ 5.0 x ULN if liver metastases, ≤ 7.0 x ULN if bone metastasis)
	  • Fasting glucose ≤ 8.3 mmol/L

	• HbA1c ≤ 7.5% • Serum albumin ≥ 30 g/L • INR ≤ 1.2 • Serum Creatinine or Creatinine clearance ≤ 1.5 x ULN or ≥ 50 mL/min; measured directly by 24-hour urine sampling or as calculated by Crockcroft and Gault equation
Critères d'exclusion	• Untreated or symptomatic CNS metastases, radiation treatment for CNS metastases within 28 days • Active inflammatory bowel disease, bowel inflammation, inability to swallow oral medication or GI condition that alters oral absorption • Prior treatment with fulvestrant, selective estrogen receptor degraders (SERDs) or known inhibitors of the PI3K pathway including PI3K inhibitors, AKT inhibitors, or mTOR inhibitors • Mean QT interval corrected for heart rate (QTc) ≥ 480 msec by ECG or history of familial long QT syndrome • Active or uncontrolled infections or serious illnesses or medical conditions • Clinically significant liver diseases • History of lung disease or history of opportunistic infections • Type 1 or Type 2 diabetes mellitus requiring insulin • Grade ≥ 2 uncontrolled hypercholesterolemia or hypertriglyceridemia • Known abnormalities in coagulation • History of hypersensitivity to the study drugs or components • Pregnant or lactating women