Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	A Phase Ib/III Randomised Study of Capivasertib Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Hormone Receptor-Positive and Human Epidermal Growth Factor Receptor 2-Negative Locally Advanced, Unresectable or Metastatic Breast Cancer
Protocole ID	CAPItello-292
ClinicalTrials.gov ID	NCT04862663
Type(s) de cancer	Sein
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Capivasertib + palbociclib et fulvestrant versus placebo + palbociclib et fulvestrant
Institution	CIUSSS DU SAGUENAY – LAC-SAINT-JEAN HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
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Statut	Fermé
But étude	A Phase Ib/III Randomised Study of Capivasertib plus Palbociclib and Fulvestrant versus Placebo plus Palbociclib and Fulvestrant in Hormone Receptor-Positive and Human Epidermal Growth Factor Receptor 2-Negative Locally Advanced, Unresectable or Metastatic Breast Cancer (CAPItello-292).

Critères d'éligibilité	**Key inclusion criteria for both phases:**
	• Adult females (pre- and/or post-menopausal), and adult males.
	• Histologically confirmed HR+/ HER2- breast cancer determined from the most recent tumour sample (primary or metastatic) per the American Society of Clinical Oncology and College of American Pathologists guideline. To fulfil the requirement of HR+ disease, a breast cancer must express ER with or without co-expression of progesterone receptor.
	• Eligible for palbociclib and fulvestrant therapy as per investigator assessment. Previous tolerance to specific CDK4/6 inhibitors and dose levels required.
	• Adequate organ and bone marrow functions.
	• Consent to provide a mandatory FFPE tumour sample.
	Inclusion criteria only for phase III:
	• Previous treatment with an ET (tamoxifen or an AI) as a single agent or in combination, with:
	  • radiological evidence of breast cancer recurrence or progression while on, or within 12 months of, completing a (neo)adjuvant ET regimen OR
	  • radiological evidence of progression while receiving the ET for locally advanced or metastatic breast cancer (this does not need to be the most recent therapy)
	• Received up to a maximum of 1 lines of prior chemotherapy in the advanced setting.

Critères d'exclusion	**Key exclusion criteria for both phases:**
	• History of another primary malignancy except for malignancy treated with curative intent with no known active disease ≥ 5 years before the first dose of study intervention and of low potential risk for recurrence.
	• Radiotherapy with a wide field of radiation within 4 weeks prior to study treatment initiation and/or radiotherapy with a limited field of radiation for palliation within 2 weeks prior to study treatment initiation. Patients who received prior radiotherapy to ≥25% of bone marrow are not eligible independent of when it was received.
	• Major surgery (excluding placement of vascular access) within 4 weeks of the first dose of study treatment.
	• Persistent toxicities (CTCAE Grade >1) caused by previous anticancer therapy, excluding alopecia. Participants with irreversible toxicity that is not reasonably expected to be exacerbated by study intervention may be included (eg, hearing loss) after consultation with the AstraZeneca study physician.
	• Spinal cord compression, brain metastases or leptomeningeal metastases unless asymptomatic, treated and stable and not requiring steroids within 4 weeks prior to study treatment initiation.
	• Any of the following cardiac criteria at screening:
	  • . Mean resting corrected QT interval (QTc) > 470 msec obtained from 3 consecutive ECGs
	  • . Any clinically important abnormalities in rhythm, conduction or morphology of resting ECG (eg, complete left bundle branch block, third-degree heart block)
	  • . Any factors that increase the risk of QTc prolongation or risk of arrhythmic events
	  • . Experience of any of the following procedures or conditions in the preceding 6 months: coronary artery bypass graft, angioplasty, vascular stent, myocardial infarction, angina pectoris, congestive heart failure New York Heart Association (NYHA) grade ≥ 2
	  • . Uncontrolled hypotension
	  • . Cardiac ejection fraction outside institutional range of normal or < 50% (whichever is higher)
	• Any of these clinically significant abnormalities of glucose metabolism at screening:
	  • . diabetes mellitus type I or type II requiring insulin treatment
	  • . HbA1c ≥ 8.0% (63.9 mmol/mol)
	• Previous allogeneic bone marrow transplant or solid organ transplant.
	Key exclusion criteria for the phase III only:
	• Any prior treatment with SERDs, AKT, PI3K or mTOR inhibitors.
	• Prior treatment with CDK4/6 inhibitors in the metastatic setting (prior CDK4/6 inhibitors permitted in the adjuvant setting).