Essai Clinique

Généré le 28 avr. 2024 à partir de http://www.geoq.info/fr/pub/essai-clinique-2964-pdf

Titre	Étude de phase III à répartition aléatoire, à double insu et contrôlée par placebo sur l'alpelisib en association avec le fulvestrant, menée chez des hommes et des femmes ménopausées atteints d'un cancer du sein avancé à récepteurs hormonaux positifs et HER2-négatif, ayant progressé pendant ou après le traitement par un inhibiteur de l'aromatase.
Protocole ID	SOLAR-1
ClinicalTrials.gov ID	NCT02437318
Type(s) de cancer	Sein
Phase	Phase III
Médicament	Alpelisib et Fulvestrant
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
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Statut	Fermé
But étude	To determine whether treatment with alpelisib plus fulvestrant prolongs progression-free survival compared to fulvestrant and placebo in men and postmenopausal women with hormone receptor positive (HR+), HER2-negative advanced breast cancer, who received prior treatment with an Aromatase Inhibitor either as (neo)adjuvant or for advanced disease.
Critères d'éligibilité	• If female, patient is postmenopausal • Patient has identified PIK3CA status • Patients may be: • relapsed with documented evidence of progression more than 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for metastatic disease • relapsed with documented evidence of progression on or within 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for metastatic disease • relapsed with documented evidence of progression more than 12 months from completion of adjuvant endocrine therapy and then subsequently progressed with documented evidence of progression after one line of endocrine therapy for metastatic disease • newly diagnosed advanced breast cancer, then relapsed with documented evidence of progression after one line of endocrine therapy • Patient has recurrence or progression of disease during or after AI therapy (i.e. letrozole, anastrozole, exemestane). • Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive breast cancer by local laboratory and has HER2 negative breast cancer • Patient has either measurable disease per RECIST 1.1 criteria OR at least one predominantly lytic bone lesion must be present • Patient has adequate bone marrow function
Critères d'exclusion	• Patient with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine therapy per the investigator's best judgment • Patient has received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant, any PI3K, mTOR or AKT inhibitor (pre-treatment with CDK4/6 inhibitors is allowed) • Patient with inflammatory breast cancer at screening • Patients with Child pugh score B or C

- Patients with an established diagnosis of diabetes mellitus type I or not controlled type II
- Patient has Eastern Cooperative Oncology Group (ECOG) performance status 2 or more
- Patient with CNS involvement unless he/she is at least 4 weeks from prior therapy completion to starting the study treatment and has stable CNS tumor at time of screening and not receiving steroids and/or enzyme inducing ant-epileptic medications for brain metastases
- Patient has participated in a prior investigational study within 30 days prior to enrollment or within 5 half-lives of the investigational product, whichever is longer.