Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	Étude de phase II multicentrique, à double insu, contrôlée par placebo et à répartition aléatoire visant à comparer l'efficacité du xentuzumab en association avec l'évérolimus et l'exémestane par rapport à celle de l'évérolimus et de l'exémestane chez des femmes ménopausées atteintes d'un cancer du sein HR+/HER2- métastatique sans atteinte viscérale
Protocole ID	XENERA-1 (1280-0022)
ClinicalTrials.gov ID	NCT03659136
Type(s) de cancer	Sein
Phase	Phase II
Type étude	Traitement
Médicament	Xentuzumab avec Everolimus et Exemestane
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
Investigateur principal	Dre Julie Lemieux
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Statut	Fermé
But étude	The main objective of the trial is to assess the anti-tumor activity of xentuzumab in combination with everolimus and exemestane over everolimus and exemestane in post menopausal patients with HR+/ HER2- advanced or metastatic breast cancer and non-visceral disease.
Critères d'éligibilité	• Documented histologically confirmed breast cancer with ERand/ or PgR-positive and HER2-negative status • Locally advanced or metastatic breast cancer not deemed amenable to curative surgery or curative radiation therapy • Archival tumour sample available at the time of informed consent and provided to the central laboratory around the time of randomisation. Patients must provide a formalin-fixed paraffin embedded (FFPE) tissue biopsy sample preferably taken at the time of presentation with recurrent or metastatic disease (provision of a biopsy sample taken from the bone is not acceptable). • Patients must satisfy the following criteria for prior therapy: • Progressed during treatment or within 12 months of completion of adjuvant therapy with an aromatase inhibitor and/or tamoxifen if post-menopausal, or tamoxifen if pre or peri-menopausal or • Progressed while on or within 1 month after the end of prior aromatase inhibitor therapy for advanced/metastatic breast cancer if post-menopausal, or prior endocrine treatment for advanced/metastatic breast cancer if pre- or peri-menopausal. • Patients must not have received more than one previous line of non-steroidal aromatase inhibitor treatment for advanced/metastatic disease. Prior treatment with one line of CDK4/6 inhibitors is allowed. • Prior treatment with fulvestrant if duration was at least 2 years in the adjuvant setting or at least 6 months in the metastatic setting is allowed. • Patients must be post-menopausal at time of signature of trial informed consent. • Patients must have • At least one measurable non-visceral lesion according to RECIST version 1.1 in either lymph nodes, soft tissue, skin and/or • At least one measurable non-visceral lesion according to RECIST version 1.1 as lytic or mixed (lytic + blastic) in bone and/or

	• At least one non-measurable lytic or mixed (lytic + blastic) bone lesion according to RECIST version 1.1 • Eastern Cooperative Oncology Group (ECOG) performance score 0 or 1. • Adequate organ function
Critères d'exclusion	• Previous treatment with agents targeting the IGF pathway, PI3K, AKT, or mTOR pathways • Prior treatment with exemestane (except adjuvant exemestane stopped >12 months prior to start of study treatment as long as the patient did not recur during or within 12 months after the end of adjuvant exemestane) • Evidence of visceral metastasis/es (i.e. liver, lung, peritoneal, pleural metastases, malignant pleural effusions, malignant peritoneal effusions) • History or evidence of metastatic disease to the brain • Leptomeningeal carcinomatosis • Any previous chemotherapy for HR+ HER2- metastatic breast cancer • Radiotherapy within 4 weeks prior to the start of study treatment • Use of concomitant systemic sex hormone therapy • History or presence of cardiovascular abnormalities • Known pre-existing interstitial lung disease • Further exclusion criteria apply