Essai Clinique

Généré le 27 avr. 2024 à partir de http://www.geoq.info/fr/pub/essai-clinique-3586-pdf

Titre	Étude de phase III avec répartition aléatoire et menée sans insu, visant à évaluer l'abémaciclib administré en association avec un traitement endocrinien adjuvant standard, comparativement à un traitement endocrinien adjuvant standard administré seul, chez des patients atteints d'un cancer du sein à un stade précoce et à risque élevé, avec envahissement ganglionnaire, récepteurs hormonaux positifs (RH+) et récepteurs 2 du facteur de croissance épidermique humain négatifs (HER2-)
Protocole ID	B-58/Monarch E/I3Y-MC-JPCF
ClinicalTrials.gov ID	NCT03155997
Type(s) de cancer	Sein
Phase	Phase III
Stade	Adjuvant
Type étude	Traitement
Médicament	Abemaciclib
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
Investigateur principal	Dre Louise Provencher
Coordonnateur	Nathalie Vaillancourt 418-682-7511 poste 2159
Statut	Fermé
But étude	The purpose of this study is to evaluate the safety and efficacy of the study drug abemaciclib in participants with high risk, node positive, early stage, hormone receptor positive (HR+), human epidermal receptor 2 negative (HER2-), breast cancer.
Critères d'éligibilité	• Women (regardless of menopausal status) or men ≥18 years of age (or per local regulations). • The participant has confirmed HR+, HER2-, early stage resected invasive breast cancer without evidence of distant metastases. • The participant must have undergone definitive surgical treatment for the current malignancy. • The participant must have tumor tissue from breast (preferred) or lymph node for exploratory biomarker analysis available prior to randomization. • The participant must have axillary lymph node involvement by tumor and have one of the following indicating a higher risk of relapse: • 4 or more axillary lymph nodes involved with cancer • Tumor size of at least 5 centimeters • Grade 3 histology • Ki67 index by central analysis of ≥20% on untreated breast tissue • The participant must be randomized within 16 months from the time of surgery. • If the participant is currently receiving or initiating standard adjuvant endocrine therapy at time of study entry, she/he must not have received more than 12 weeks of adjuvant endocrine therapy following his/her last non-endocrine therapy (surgery, chemotherapy, or radiation). • Participants must have recovered from the acute effects of chemotherapy and radiotherapy and from surgical side effects following definitive breast surgery. • Women of reproductive potential must have a negative blood pregnancy test and agree to use highly effective contraceptive methods. • The participant has a Eastern Cooperative Oncology Group (ECOG) performance status ≤1. • The participant has adequate organ function.

	• The participant is able to swallow oral medications.
Critères d'exclusion	• Stage IV (M1), Stage IA, and lymph node negative breast cancer. • Participants with a history of previous breast cancer are excluded, with the exception of lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS) treated by locoregional therapy alone ≥5 years ago. Participants with a history of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix), unless in complete remission with no therapy for a minimum of 5 years are excluded. • Females who are pregnant or lactating. • The participant has previously received treatment with any CDK4 and CDK6 inhibitor. • The participant is receiving concurrent exogenous reproductive hormone therapy (for example, birth control pills, hormone replacement therapy, or megestrol acetate). • The participant has previously received endocrine therapy for breast cancer prevention (tamoxifen or raloxifene or aromatase inhibitors). • The participant has serious preexisting medical condition(s) that, in the judgment of the investigator, would preclude participation in this study. • The participant has a personal history of any of the following conditions: syncope of cardiovascular etiology, ventricular arrhythmia of pathological origin or sudden cardiac arrest. Any participant with a history of venous thromboembolism (VTE) (for example, deep vein thrombosis [DVT] of the leg or arm and/or pulmonary embolism) will be excluded. • The participant has active bacterial infection, fungal infection, or detectable viral infection or viral load. • The participant has received an experimental treatment in a clinical trial within the last 30 days or 5 half-lives, whichever is longer.