




Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant, a Next Generation, Oral Selective Estrogen Receptor Degradar) vs Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients With ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease
Protocole ID	CAMBRIA-2
ClinicalTrials.gov ID	NCT05952557
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Camizestrant versus hormonothérapie standard
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL  HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
Investigateur principal	Dre Julie Lemieux
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Statut	Actif en recrutement
Date d'activation	10-01-2024
But étude	This is a Phase III open-label study to assess if camizestrant improves outcomes compared to standard adjuvant endocrine therapy for patients with ER+/HER2- early breast cancer with intermediate-high or high risk for disease recurrence who completed definitive locoregional therapy (with or without chemotherapy). The planned duration of treatment in either arm within the study will be 7 years.
Critères d'éligibilité	<ul style="list-style-type: none">• Women and Men; ≥18 years at the time of screening (or per national guidelines)• Histologically confirmed ER+/HER2- early-stage resected invasive breast cancer with absence of any evidence of metastatic disease as defined in the protocol.• Completed adequate (definitive) locoregional therapy (surgery with or without radiotherapy) for the primary breast tumour(s), with or without (neo)adjuvant chemotherapy.• Patients must be randomised within 12 months of definitive breast surgery.• Patients may have received up to 12 weeks of endocrine therapy prior to randomisation.• Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1• Adequate organ and bone marrow function
Critères d'exclusion	<ul style="list-style-type: none">• Inoperable locally advanced or metastatic breast cancer• Pathological complete response following treatment with neoadjuvant therapy• History of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix or considered a very low risk of recurrence per investigator judgement) unless in complete remission with no therapy for a minimum of 5 years from the date of randomisation• Any evidence of severe or uncontrolled systemic diseases which, in the investigator's opinion precludes participation in the study or compliance "• Known LVEF <50% with heart failure NYHA Grade ≥2.• Mean resting QTcF interval > 480 ms at screening• Concurrent exogenous reproductive hormone therapy or non topical hormonal therapy for

non-cancer-related conditions

- Any concurrent anti-cancer treatment not specified in the protocol with the exception of bisphosphonates (e.g. zoledronic acid) or RANKL inhibitors (eg, denosumab)
- Previous treatment with camizestrant, investigational SERDs/investigational ER targeting agents, or fulvestrant
- Currently pregnant (confirmed with positive serum pregnancy test) or breastfeeding.
- Patients with known hypersensitivity to active or inactive excipients of camizestrant or drugs with a similar chemical structure or class to camizestrant. In pre-/peri-menopausal female and male patients, known hypersensitivity or intolerance to LHRH agonists that would preclude the patient from receiving any LHRH agonist.