Essai Clinique

Généré le 22 mai 2025 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 Degrader) 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	• 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	• 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.