Essai Clinique

Généré le 27 avr. 2025 à partir de

Titre	A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy With Camizestrant Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients With ER+/HER2- Early Breast Cancer
Protocole ID	CAMBRIA-1
ClinicalTrials.gov ID	NCT05774951
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Camizestrant versus traitement endocrinien standard
Institution	CISSS DES LAURENTIDES HOPITAL DE SAINT-JEROME 290 Rue de Montigny, Saint-Jérôme, QC, J7Z 5T3
Ville	
Investigateur principal	Dr Ghislain Cournoyer
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Statut	Actif en recrutement
Date d'activation	16-02-2024
But étude	This is a Phase III open-label study to assess if camizestrant improves outcomes compared to standard endocrine therapy in patients with ER+/HER2 - early breast cancer with intermediate or high risk for disease recurrence who completed definitive locoregional therapy (with or without chemotherapy) and standard adjuvant endocrine therapy (ET) for at least 2 years and up to 5 years. The planned duration of treatment in either arm of the study is 60 months.
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 high or intermediate risk of recurrence, based on clinical-pathological risk features, 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 • Completed at least 2 years but no more than 5 years (+3 months) of adjuvant ET (+/- CDK4/6 inhibitor) • Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 • Adequate organ and 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 at 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