




Essai Clinique

Généré le 21 mai 2024 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	<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 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	<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 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