Essai Clinique

Généré le 21 mai 2025 à partir de

Titre	A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients Who Have Previously Received 2 to 5 Years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer With an Increased Risk of Recurrence
Protocole ID	EMBER-4
ClinicalTrials.gov ID	NCT05514054
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Imlunestrant versus thérapie endocrinienne adjuvante standard
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Rami Younan
Coordonnateur	Ana Lydia Tkalec 514-890-8000 poste 14186
Statut	Actif en recrutement
Date d'activation	20-10-2023
But étude	The main purpose of this study is to measure how well imlunestrant works compared to standard hormone therapy in participants with early breast cancer that is estrogen receptor positive (ER+) and human epidermal receptor 2 negative (HER2-). Participants must have already taken endocrine therapy for two to five years and must have a higher-than-average risk for their cancer to return. Study participation could last up to 10 years.
Critères d'éligibilité	• Have a diagnosis of ER+, HER2- early-stage, resected, invasive breast cancer without evidence of distant metastasis. • Participants must have received at least 24 months but not more than 60 months of any adjuvant ET, from time of adjuvant ET initiation. • Participants may have received (neo) adjuvant chemotherapy and/or targeted therapy with a CDK4/6- or PARP- inhibitor. • Must have an increased risk of disease recurrence based on clinical-pathological risk features. • Have a Performance Status of 0 or 1 on the Eastern Cooperative Oncology Group scale. • Have adequate organ function.
Critères d'exclusion	• Have any evidence of metastatic disease (including contralateral ALN) or inflammatory breast cancer at primary breast cancer diagnosis. • Participants with more than a 6-month consecutive gap in therapy during the course of prior adjuvant ET. • Participants who have completed or discontinued prior adjuvant ET >6 months prior to screening. • Participants with a history of previous breast cancer are excluded, with the exception of ipsilateral DCIS treated by locoregional therapy alone ≥5 years ago. • Pregnant, breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 180 days after the last dose of study intervention. • Participant has previously received ET of any duration for breast cancer prevention (tamoxifen or AIs) or raloxifene. • Participants with a history of any other cancer.

- Have serious preexisting medical conditions that, in the judgment of the investigator, would preclude participation in this study.