Essai Clinique

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Titre	A Phase II, Single-Arm Study of Giredestrant in Patients With Grade 1 Endometrial Cancer
Protocole ID	EndomERA
ClinicalTrials.gov ID	NCT05634499
Type(s) de cancer	Endomètre
Phase	Phase II
Type étude	Clinique
Médicament	Giredestrant
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dre Susie Lau
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Statut	Actif en recrutement
Date d'activation	12-10-2023
But étude	This Phase II, global, single-arm study is designed to evaluate the efficacy, safety, and pharmacokinetics of giredestrant monotherapy in participants with Grade 1 endometrioid endometrial cancer.
Critères d'éligibilité	• Confirmed Grade 1 endometrial cancer (EC) of endometrioid histology for which participants are willing to receive 6-cycles of study therapy. An endometrial biopsy (EMB) or dilation and curettage (D&C) fresh collected within the screening period or archival sample collected within 2 months prior to screening must be provided to a central laboratory for histologic confirmation to determine eligibility. • Life expectancy ≥12 weeks • Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 • Magnetic resonance imaging (MRI)-confirmation of non-deeply invasive tumor (<50% myometrial invasion) • MRI or computed tomography (CT)-confirmation of no extrauterine disease • Willing to undergo a minimum of 6 continuous cycles of therapy before decision on surgery • No prior treatment for endometrial cancer • Able and willing to take oral medications • Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures • Adequate hematologic and end-organ function, as defined in the protocol • Negative HIV test at screening • For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agree to refrain from donating eggs, during the treatment period and for 30 days after the final dose of giredestrant, as defined in the protocol

Critères d'exclusion	• Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 30 days after the final dose of giredestrant or within the time period specified per local prescribing guidelines after the final dose of the investigator's choice of endocrine therapy • Participants with non-endometrioid histologies, such as serous, clear cell, and mixed • Treatment with investigational therapy within 28 days prior to initiation of study enrollment • Treatment for cancer including but not limited to, chemotherapy, immunotherapy, cyclin-dependent kinase (CDK)4/6 inhibitors, endocrine therapy, biologic therapy, or herbal therapy within 28 days prior to the initiation of study enrollment • Any gastrointestinal condition causing malabsorption or obstruction (e.g., celiac sprue, gastric bypass surgery, strictures, adhesions, history of small bowel resection, blind loop syndrome) • Has been on any hormonal treatment (including progestin-containing intrauterine device [IUD]) for complex atypical hyperplasia (CAH)/EIN or Grade 1 EC in the last 3 months • Use hormone replacement therapy (including systemic or topical estrogen, progesterone, or testosterone based medication) or/and phytoestrogen supplements (i.e., black cohosh) or has been on progestin (including progestin-containing IUD), tamoxifen or aromatase inhibitor within the prior 3 months • Known hypersensitivity to giredestrant or its excipients • Known intercurrent illness or psychiatric illness/social situations that will limit compliance with study requirements • Evidence or high suspicion of metastatic/extrauterine disease at enrollment • Unwilling or unable to comply with study-related procedures, including all endometrial sampling/biopsies • Planned surgery, either for the treatment of cancer or any other surgery, during the study treatment period and up to 10 days after the completion of study treatment • Serious infections requiring IV antibiotics within 7 days prior to initiation of study treatment or any active infection that, in the opinion of the investigator, could impact participant safety • Participants who have clinically significant liver disease consistent with Child-Pugh Class B or C, including active hepatitis (e.g., hepatitis B virus [HBV] or hepatitis C virus [HCV]), current alcohol abuse, cirrhosis, or positive test for viral hepatitis, as defined in the protocol • Treatment with strong CYP3A4 inhibitors or inducers within 14 days or 5 drug elimination half-lives (whichever is longer) prior to initiation of study treatment • Substance abuse within 12 months prior to screening • Any serious medical condition or abnormality in clinical laboratory tests that precludes the participant's safe participation in and completion of the study • History of other malignancy within 5 years prior to screening, except for those with an expected negligible risk for metastases or death (e.g., 5-year overall survival 90%) after curative treatment • Active tuberculosis • Severe infection per investigator judgment at the time of enrollment, including but not limited to, use of systemic antibiotics, hospitalization for complications of infection, bacteremia, or severe pneumonia, or any active infection that, in the opinion of the investigator, could impact participant safety • Significant cardiovascular disease, such as cardiac disease New York Heart Association Class II or greater, myocardial infarction, or cerebrovascular accident within 3 months prior to enrollment, unstable arrhythmias, or unstable angina • Active cardiac disease or history of cardiac dysfunction, as defined in the protocol • Major surgical procedure other than for diagnosis within 28 days prior to enrollment or anticipation of need for a major surgical procedure during the study • Prior allogeneic bone marrow transplantation or solid organ transplant • Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or renders the participant at high risk for treatment complications illnesses or conditions that interfere with the participant's capacity to understand, follow, and/or comply with study procedures