Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude de phase III multicentrique, à double insu et à répartition aléatoire visant à évaluer le dostarlimab (TSR-042) en association avec la bithérapie carboplatine-paclitaxel par rapport à un placebo avec la bithérapie carboplatine-paclitaxel chez des patientes atteintes d'un cancer de l'endomètre récurrent ou primaire avancé
Protocole ID	RUBY/ENGOT-EN6
ClinicalTrials.gov ID	NCT03981796
Type(s) de cancer	Endomètre
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Dostarlimab + carboplatine-paclltaxel vs placebo + carboplatine-paclitaxel
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dre Lucy Gilbert
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Statut	Fermé
But étude	This is a Phase 3, randomized, double-blind, multicenter study to evaluate the efficacy and safety of dostarlimab plus carboplatin-paclitaxel versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced (Stage III or IV) endometrial cancer.
Critères d'éligibilité	• Female subject is at least 18 years of age. • Subject has histologically or cytologically proven endometrial cancer with recurrent or advanced disease. • Subject must have primary Stage III or Stage IV disease or first recurrent endometrial cancer with a low potential for cure by radiation therapy or surgery alone or in combination. • Subject has an ECOG performance status of 0 or 1. • Subject has adequate organ function.
Critères d'exclusion	• Subject has received neo-adjuvant/adjuvant systemic chemotherapy for primary Stage III or IV disease and: • has not had a recurrence or PD prior to entering the study OR • has had a recurrence or PD within 6 months of completing chemotherapy treatment prior to entering the study • Subject has had > 1 recurrence of endometrial cancer. • Subject has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent. • Subject has received prior anticancer therapy within 21 days or < 5 times the half-life of the most recent therapy prior to Study Day 1, whichever is shorter. • Subject has a concomitant malignancy, or subject has a prior non-endometrial invasive malignancy who has been disease-free for < 3 years or who received any active treatment in the last 3 years for that malignancy. • Subject has known uncontrolled central nervous system metastases, carcinomatosis meningitis, or both.

- Subject has a known history of human immunodeficiency virus.
- Subject has known active hepatitis B or hepatitis C.
- Subject has an active autoimmune disease that has required systemic treatment in the past 2 years.
- Subject has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of systemic immunosuppressive therapy within 7 days prior to the first dose of study treatment.
- Subject has not recovered from cytotoxic therapy-induced AEs.
- Subject has not recovered adequately from AEs or complications from any major surgery prior to starting therapy.