




# Essai Clinique

Généré le 27 avr. 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	<a href="https://clinicaltrials.gov/ct2/show/study/NCT03981796">NCT03981796</a>
Type(s) de cancer	Endomètre
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Dostarlimab + carboplatine-paclitaxel vs placebo + carboplatine-paclitaxel
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL  L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dre Marie Plante
Coordonnateur	Maryse Gingras 418-691-5781
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	<ul style="list-style-type: none"><li>• Female subject is at least 18 years of age.</li><li>• Subject has histologically or cytologically proven endometrial cancer with recurrent or advanced disease.</li><li>• 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.</li><li>• Subject has an ECOG performance status of 0 or 1.</li><li>• Subject has adequate organ function.</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• Subject has received neo-adjuvant/adjuvant systemic chemotherapy for primary Stage III or IV disease and:</li><li>• has not had a recurrence or PD prior to entering the study OR</li><li>• has had a recurrence or PD within 6 months of completing chemotherapy treatment prior to entering the study</li><li>• Subject has had &gt; 1 recurrence of endometrial cancer.</li><li>• Subject has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent.</li><li>• Subject has received prior anticancer therapy within 21 days or &lt; 5 times the half-life of the most recent therapy prior to Study Day 1, whichever is shorter.</li><li>• Subject has a concomitant malignancy, or subject has a prior non-endometrial invasive malignancy who has been disease-free for &lt; 3 years or who received any active treatment in the last 3 years for that malignancy.</li><li>• Subject has known uncontrolled central nervous system metastases, carcinomatosis meningitis, or both.</li></ul>

- 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.