Essai Clinique

Généré le 27 avr. 2025 à partir de

Titre	A Multicenter Phase 3, Double-Blind, Placebo-Controlled Study Comparing Chemo-Immunotherapy (Paclitaxel-Carboplatin- Oregovomab) vs Chemotherapy (Paclitaxel-Carboplatin- Placebo) in Patients With Advanced Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma
Protocole ID	FLORA-5
ClinicalTrials.gov ID	NCT04498117
Type(s) de cancer	Ovaire
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Chimio-Immunothérapie (paclitaxel - carboplatine - oregovomab) vs Chimiothérapie (paclitaxel - carboplatine - placebo)
Institution	CISSS DE LAVAL HOPITAL DE LA CITE-DE-LA-SANTE 1755 boul. René-Laennec, Laval, QC, H7M 3L9
Ville	
Investigateur principal	Dre Mélanie Arbour-Levert
Coordonnateur	Solange Tremblay 450-668-1010 poste 23603
Statut	Fermé
But étude	Study to compare the safety and efficacy of oregovomab versus placebo, administered in combination with specific cycles of a standard six-cycle chemotherapy regimen (paclitaxel and carboplatin), for the treatment of subjects with newly diagnosed advanced ovarian cancer who have undergone optimal debulking.

Critères d'éligibilité	Major Inclusion Criteria:
	• Adults 18 years old or older.
	• Newly diagnosed epithelial adenocarcinoma of ovarian, fallopian tube or peritoneal origin FIGO Stage III or IV disease.
	• Histologic epithelial cell types: high grade serous adenocarcinoma, high grade endometrioid adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, or adenocarcinoma not otherwise specified (N.O.S.).
	• Completed debulking surgery (either primary debulking surgery or interval debulking surgery at the discretion of the investigator). Debulking surgery must be optimal, R1 or R0 (defined as R1, macroscopic no greater than 1 cm in diameter, or R0, microscopic or no evidence of tumor).
	• Preoperative serum CA- 125 levels ≥ 50 U/mL.
	• Adequate bone marrow function:
	  • Absolute neutrophil count (ANC) greater than or equal to 1,500/µL
	  • Platelets greater than or equal to100,000/µL
	  • Hemoglobin greater than or equal to 8.0 g/dL (Note: Blood transfusion is permitted up to 48 hours before first dose of study treatment).
	• Adequate liver function:
	  • Bilirubin < 1.5 times upper limit normal (ULN)
	  • Lactate Dehydrogenase (LDH), SGOT/AST and SGPT/ALT < 2.5 times ULN
	  • Albumin >3.5 g/dL
	• Adequate renal function: a. Creatinine less than or equal to1.5 times ULN
	• ECOG Performance Status of 0 or 1.

Critères d'exclusion	Major Exclusion Criteria:
	• BRCA1 or BRCA2 germline gene mutation test result with:
	  • Positive, ambiguous or inconclusive result available within 28 days prior to starting study treatment, or
	  • Known BRCA1 and BRCA2 somatic mutations, and known positive germline, or
	  • Somatic Homologous Recombination Deficiency (HRD) who will receive PARP inhibitor front-line maintenance therapy.
	• Subjects with mucinous adenocarcinoma and low- grade adenocarcinoma.
	• Female subjects who are lactating and breastfeeding, or have a positive serum pregnancy test within 7 days prior to the first dose of study treatment (C1D1 for Cohort 1 or C4D1 for Cohort 2).
	• Active autoimmune disease, such as rheumatoid arthritis, systemic lupus erythematosus (SLE), ulcerative colitis, Crohn's Disease, multiple sclerosis (MS), or ankylosing spondylitis requiring active disease modifying treatment.
	• Known allergy to murine proteins or hypersensitivity to any of the excipients of the oregovomab, paclitaxel, or carboplatin.
	• Chronically treated with immunosuppressive drugs such as cyclosporine, adrenocorticotropic hormone (ACTH), etc. (see Appendix G).
	• Chronic therapeutic corticosteroid use, defined as > 5 days of prednisone or equivalent, with the exception of inhalers or those on a pre-planned steroid taper. (Note: Premedication with corticosteroids per institutional standard of care is allowed.)
	• Recognized acquired, hereditary, or congenital immunodeficiency disease, including cellular immunodeficiencies, hypogammaglobulinemia or dysgammaglobulinemia.
	• Anticipated treatment with any other anti-cancer medications, including bevacizumab, poly (ADP- ribose) polymerase (PARP) inhibitors, or any investigational agent(s) during the study.