Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Phase II, Open-Label, Multicenter, Platform Study Evaluating the Efficacy and Safety of Biomarker-Driven Therapies in Patients With Persistent or Recurrent Rare Epithelial Ovarian Tumors
Protocole ID	BOUQUET (WO42178, GOG-3051,ENGOT-GYN2)
ClinicalTrials.gov ID	NCT04931342
Type(s) de cancer	Ovaire
Phase	Phase II
Type étude	Clinique
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dre Lucy Gilbert
Coordonnateur	Phuong-Nam (Nathalie) Nguyen 514-934-1934 poste 31975
Statut	Actif en recrutement
Date d'activation	20-07-2022
But étude	This study will evaluate the efficacy and safety of multiple biomarker-selected treatments in patients with persistent or recurrent rare epithelial ovarian, fallopian tube, or primary peritoneal tumors. Enrollment will take place in two phases: a preliminary phase followed by a potential expansion phase.
Critères d'éligibilité	• Persistent or recurrent EOC that meets the following criteria: Histologically confirmed non-high-grade serous, non-high-grade endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer, including but not limited to low-grade serous ovarian carcinoma, clear cell carcinoma, mucinous carcinoma, carcinosarcoma, undifferentiated carcinoma, seromucinous carcinoma, malignant Brenner tumors, Grades 1 or 2 endometrioid carcinoma, mesonephric-like adenocarcinoma and small cell carcinoma of the ovary, hypercalcemic type (SCCOHT). Disease that is not amenable to curative surgery • Measurable disease (at least one target lesion) according to RECIST v1.1 • Previous treatment with one to four lines of therapy, at least one of which was platinum-based. Hormonal therapy does not count as a line of therapy. • Platinum-resistant disease, defined as disease progression during or within 6 months of last platinum therapy, with the following exception: Participants with primary platinum-refractory disease are excluded. • Submission of a representative tumor specimen that is suitable for next-generation sequencing (NGS) testing and estrogen receptor immunohistochemistry (ER IHC) to determine treatment arm assignment and for central pathology review. • Submission of the local pathology report and, if available, any associated stained slides that supported the local diagnosis of the histology (to be used for central pathology review) • Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 • Adequate hematologic and end-organ function • For women of childbearing potential: agreement to remain abstinent or use contraception, and agreement to refrain from donating eggs (if applicable) • In addition to the general inclusion criteria above, participants must meet all of the arm-specific inclusion criteria for the respective arm

Critères d'exclusion	• Pregnant or breastfeeding, or intending to become pregnant or breastfeed during the study • Primary platinum-refractory disease, defined as progression during or within 4 weeks after the last dose of the first-line platinum treatment • Histologic diagnosis of high-grade serous or high-grade endometrioid ovarian, fallopian tube, or primary peritoneal cancer • Current diagnosis of solely borderline epithelial ovarian tumor • Current diagnosis of non-epithelial ovarian tumors • Current diagnosis of synchronous primary endometrial cancer • Prior history of primary endometrial cancer, with the following exception: a prior diagnosis of primary endometrial cancer is permitted if it meets all of the following conditions: Stage IA, no lymphovascular invasion, International Federation of Gynecology and Obstetrics Grade 1 or 2, not a high-grade subtype. • Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures • Symptomatic, untreated, or actively progressing CNS metastases • Severe infection within 4 weeks prior to initiation of study treatment • Treatment with chemotherapy, radiotherapy, antibody therapy or other immunotherapy, gene therapy, vaccine therapy, or investigational therapy within 28 days prior to initiation of study treatment • Treatment with hormonal therapy within 14 days prior to initiation of study treatment • In addition to the general exclusion criteria above, participants can not meet any of the arm-specific exclusion criteria for the respective arm