Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	A Phase 2 Study of VS-6766 (Dual RAF/MEK Inhibitor) Alone and In Combination With Defactinib (FAK Inhibitor) in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)
Protocole ID	RAMP-201 (ENGOT-ov60)
ClinicalTrials.gov ID	NCT04625270
Type(s) de cancer	Ovaire
Phase	Phase II
Type étude	Clinique
Médicament	VS-6766 seul ou en association avec defactinib
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Diane Provencher
Coordonnateur	Bonny Choy 514-890-8000 poste 24672
Statut	Actif en recrutement
But étude	This study will assess the safety and efficacy of VS-6766 monotherapy and in combination with Defactinib in subjects with recurrent Low-Grade Serous Ovarian Cancer (LGSOC)
Critères d'éligibilité	• Histologically proven LGSOC (ovarian, peritoneal) • In Part A KRAS mutation, KRAS wt • Progression or recurrence of LGSOC after at least one prior systemic therapy for metastatic disease. • Measurable disease according to RECIST 1.1 • An Eastern Cooperative Group (ECOG) performance status ≤ 1. • Adequate organ function • Adequate recovery from toxicities related to prior treatments • Agreement to use highly effective method of contraceptive
Critères d'exclusion	• Systemic anti-cancer therapy within 4 weeks of the first dose of study therapy • Co-existing high-grade ovarian cancer or another histology • History of prior malignancy with recurrence <3 years from the time of enrollment • Major surgery within 4 weeks • Symptomatic brain metastases requiring steroids or other interventions • Known SARS-Cov2 infection (clinical symptoms) ≤28 days prior to first dose of study therapy • For subjects with prior MEK exposure, Grade 4 toxicity deemed related to the MEK inhibitor • Active skin disorder that has required systemic therapy within the past year • History of rhabdomyolysis • Concurrent ocular disorders • Concurrent heart disease or severe obstructive pulmonary disease • Subjects with the inability to swallow oral medications