

GOG-3097/ENGOT-ov81/RAMP 301: A Phase 3, Randomized, Open-Label Study of Combination Therapy with Avutometinib plus Defactinib Versus Investigator's Choice of Treatment in Patients with Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)

Study Overview:

This international, randomized, open-label, Phase 3 study will compare the investigational combination of avutometinib plus defactinib versus Investigator's Choice of Treatment options (ICT) in patients with recurrent (previously treated) LGSOC who have progressed on a prior platinum-based therapy. Avutometinib and defactinib are both called kinase inhibitors which is a type of drug that may block cancer cell growth.

The purpose of the study is to assess how avutometinib plus defactinib compares to the standard treatments for LGSOC. The study will measure effectiveness, including overall response rate (how well the combination reduces tumor size) and safety. The study will also include quality of life assessments by the patient. Gynecological cancer specialists are conducting the study.

Patients who are eligible and agree to participate in this study will be randomly assigned to receive either the investigational combination of avutometinib plus defactinib or one of five treatment options (selected by their doctor) considered standard treatments for recurrent LGSOC. Patients will have scheduled study visits to monitor their safety and how their disease is responding to the assigned treatment. Patients who are assigned to one of the standard treatments and experience progressive disease may be eligible to receive the investigational combination avutometinib plus defactinib.

Avutometinib and defactinib are investigational drugs and not approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority, either as a single agent or in combination.

Protocol Title:

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Study (Protocol) Numbers: VS-6766-301 (Verastem, Inc.)

Clinical Trial NCT06072781D

GOG-3097 (The GOG Foundation)

ENGOT-ov81/NCRI (European Network for Gynaecological Oncological Trial groups)

Study Drugs or Compounds: avutometinib (VS-6766) and defactinib (VS-6063) or Investigator's Choice of Treatment

Study Phase: Phase 3

Total Enrollment: Approximately 270 patients

Study Short Title: A Phase 3 study of avutometinib and defactinib versus investigator's choice of treatment in recurrent low-grade serous ovarian cancer

