

RAMP 201: A Phase 2 Study of Avutometinib (Dual RAF/ MEK Inhibitor In Combination with Defactinib (FAK Inhibitor) in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)

Study Overview:

The purpose of the first part of the RAMP 201 study (or trial) was to see whether an investigational drug called avutometinib (VS-6766), given to patients with recurrent LGSOC with and without a KRAS mutation, works better alone or when given in combination with a second investigational drug, defactinib. Avutometinib and defactinib are both a type of drug called a kinase inhibitor. Kinase inhibitors block cancer cell growth. The second phase of the RAMP 201 study focuses on the impact of the combination of avutometinib and defactinib. The trial will measure effectiveness, including overall response rate, as well as safety. The study is being conducted by gynecological cancer specialists.

Patients who are eligible and agree to participate in this study will be treated with a combination of avutometinib with defactinib, with follow up appointments. This is an open-label trial. Every patient will be treated with active oral study drugs, and their investigator will not be comparing it to a placebo.

Avutometinib and defactinib are investigational drugs that have not been approved by the U.S. Food and Drug Administration (FDA).

Study (Protocol) Title:

RAMP 201: A Phase 2 Study of Avutometinib (Dual RAF/MEK Inhibitor In Combination with Defactinib (FAK Inhibitor) in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)

Study (Protocol) Numbers: VS-6766-201 (Verastem, Inc.)

Clinical Trial NCT04625270

ENGOT-ov60/NCRI (European Network for Gynaecological Oncological Trial groups)

GOG-3052 (The GOG Foundation)

Study Drugs or Compounds: avutometinib (VS-6766) and defactinib (VS-6063)

Study Phase: Phase 2

Total Enrollment: Estimated at 184 patients

Study Short Title: A Phase 2 Study of Avutometinib (VS-6766) In Combination with Defactinib in Recurrent Low- Grade Serous Ovarian Cancer (LGSOC)

Sponsor: Verastem Oncology

