A Phase 1 trial of defactinib and avutometinib (VS-6766) (FRAME) - LGSOC expansion cohort

Study Overview:

This dose expansion phase will evaluate the recommended phase II dose of the combination of Avutometinib (VS-6766; RO5126766) and Defactinib (VS-6063), as decided in the dose escalation phase in patients with LGSOC (20 patients). Avutometinib and defactinib are both a type of drug called kinase inhibitors. Kinase inhibitors block cancer cell growth.

This is an open-label trial. Every patient will be treated with active 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: FRAME: A Phase I trial of the combination of Defactinib (VS-6063) (FAK inhibitor) and avutometinib (VS-6766; RO5126766) (a dual RAF/MEK inhibitor) in patients with advanced solid tumours.

Short Title: FRAME

Study (Protocol) Numbers:

ICR protocol ID: CCR4642

Verastem protocol ID: IST-VS-6063-003

Clinical Trial: NCT03875820

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

Study Phase: Phase 1 with experimental dose expansion cohorts

Total Enrollment: LGSOC expansion cohort 20 patients

Sponsor: Institute of Cancer Research, United Kingdom

Collaborators: Verastem Oncology

Principle Investigator: Udai Banerji