



A Phase 1 Trial of Avutometinib (VS-6766) alone and in combination with everolimus (RAF/MEK) – NSCLC expansion cohort

Study Overview:

This expansion cohort will evaluate the use of avutometinib (VS-6766) and everolimus in patients with KRAS-mutant lung cancer. Avutometinib and everolimus 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 is an investigational drug that have not been approved by the U.S. Food and Drug Administration (FDA). Everolimus is an FDA approved therapy for some forms of cancer; however, has not been approved for use in non-small-cell lung cancer (NSCLC).

Study (Protocol) Title: A Phase I trial of avutometinib (VS-6766; RO5126766) (a dual RAF/MEK inhibitor) exploring intermittent, oral dosing regimens in patients with solid tumours or multiple myeloma, with an expansion to explore intermittent dosing in combination with Everolimus

Short Title: RAF/MEK

Study (Protocol) Numbers:

ICR protocol ID: CCR3808

Verastem ID: IST-VS-6766-002

Clinical Trial: NCT02407509

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

Study Phase: Phase 1 with experimental dose expansion cohorts

Total Enrollment: NSCLC expansion cohort 20 patients

Sponsor: Royal Marsden NHS Foundation Trust

Collaborators: Institute of Cancer Research, United Kingdom, Verastem Oncology, Chugai Pharmaceutical

Principle Investigator: Udai Banerji