



A Single Arm Phase 1/2 Trial of abemaciclib + avutometinib (VS-6766) + fulvestrant in Metastatic HR+/HER2- Breast Cancer

Study Overview:

The purpose of this Phase 1/2 study is to examine the safety and efficacy of the combination of avutometinib (VS-6766), abemaciclib, and fulvestrant in treating metastatic hormone receptor-positive and HER2-negative (HR+/HER2-) breast cancer. Avutometinib is a type of drug called a kinase inhibitor that blocks 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 has not been approved by the U.S. Food and Drug Administration (FDA). The FDA has approved both abemaciclib and fulvestrant as treatment options for breast cancer.

Study (Protocol) Title: A Single Arm Phase 1/2 Trial of abemaciclib + avutometinib (VS-6766) + fulvestrant in Metastatic HR+/HER2- Breast Cancer

Study (Protocol) Numbers:

Verastem ID: IST-VS-6766-005

Clinical Trial: NCT05608252

Study Drugs or Compounds: avutometinib (VS-6766), abemaciclib, & fulvestrant

Study Phase: Phase 1/2

Total Enrollment: estimated at 63 patients

Sponsor: Adrienne G. Waks, Dana-Farber Cancer Institute (DFCI)

Collaborators: Verastem Oncology & Eli Lilly and Company

Principle Investigator: Adrienne G. Waks