Recruiting Now!

A 6-Week, Randomized, Double-Blind, Sponsor-Open Study to Assess the Effect of Repeated Subcutaneous Administration of PF-06946860 on Appetite in Participants with Advanced Cancer and Anorexia, Followed by an 18-Week, Open-Label Treatment Period

This 6-week, double-blind study will compare the effects of PF-06946860 and a placebo on appetite and find out how participants with advanced cancer and anorexia feel after receiving repeated subcutaneous (SC) doses.

PF-06946860 is an investigational compound. These are not the complete inclusion/exclusion criteria. This information is current as of April 2021.

Patient Population/ Key Inclusion Criteria

- N=40
- Anorexia as defined by a score of ≤5 on a 7-day recall appetite scale (0-10)
- Documented diagnosis of non-small cell lung, pancreatic, colorectal, prostate, breast or ovarian cancer which, in the treating oncologist's assessment, is considered incurable
- Signed informed consent

Experimental	Placebo
PF-06946860 treatment followed by Open-label PF-06946860 treatment by SC injection	Placebo treatment followed by Open-label PF-06946860 treatment by SC injection

Prior/Concomitant Therapies

- Meets any one of the following criteria at Randomization:
  - Not currently receiving antineoplastic therapy
  - On third-line systemic antineoplastic therapy
  - Receiving chemotherapy or immunotherapy treatment, which is considered to be without curative intent
  - On a stable regimen of systemic antineoplastic therapy
- May be on a stable regimen of concomitant therapies such as mirtazapine, olanzapine, cannabinoids or megestrol acetate

Key Exclusion Criteria

- Other forms of cancer not listed in Inclusion Criterion for which treatment has been received in the past 6 months
- Receiving tube feedings or parenteral nutrition at the time of Screening or Randomization
- Current active reversible causes of decreased food intake
- Participants with known symptomatic brain metastases requiring steroids
- Active uncontrolled bacterial, fungal or viral infection, including HBV, HCV
- Confirmed positive test for HIV
- Elevated blood pressure uncontrolled by medications
- Inadequate renal and liver function
- Women who are pregnant or breastfeeding

Primary Endpoint

- Effect of PF-06946860 compared to placebo on appetite
  - Change from baseline for patient reported 7-day recall Cancer Related Cachexia Symptom Assessment–Appetite score at Week 4

Secondary Endpoints

- The safety and tolerability of repeated subcutaneous administrations of PF-06946860 and the effect on fatigue will also be examined. For details of secondary endpoints, please visit clinicaltrials.gov (NCT04803305)

Find out more at clinicaltrials.gov
NCT04803305