Phase II Trial to Evaluate Pemigatinib in Patients with Solid Tumor Malignancy

Official Title: A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib in Participants With Previously Treated Locally Advanced/Metastatic or Surgically Unresectable Solid Tumor Malignancies Harboring Activating FGFR Mutations or Translocations (FIGHT-207)

The purpose of this study is to evaluate the efficacy and safety of pemigatinib which will be administered orally everyday.

Pemigatinib is an inhibitor of the FGFR family of receptor tyrosine kinases that is proposed for the treatment of solid tumor malignancies with an activating FGFR mutation or translocation. FGFR contributes to the development of malignancies by promoting tumor cell proliferation, survival, migration, and angiogenesis.

Preclinical and clinical data support the use of FGFR inhibitors in FGFR altered cell lines and tumors derived from a variety of cancer types. For this reason, administering pemigatinib will allow consistent inhibition of the aberrant FGFR receptor in this population.

Key Inclusion Criteria:
- Histologically or cytologically confirmed tumor malignancy that is advanced or metastatic, or is surgically unresectable.
- Age ≥18.
- Documentation of an FGFR1-3 gene mutation or translocation
- Baseline archival tumor specimen (if less than 12 months from date of screening) or willingness to undergo a pretreatment tumor biopsy to obtain specimen

Key Exclusion Criteria:
- Prior receipt of a selective FGFR inhibitor
- Current evidence of clinically significant corneal or retinal disorder
- Untreated brain/CNS metastases or CNS metastases that have progressed.
  Note: Participants with progressing primary brain tumors are allowed if they have no new neurological symptoms

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