Protocol Title: A Phase 1/1b Study of MGCD516 in Patients with Advanced Solid Tumor Malignancies

Target Population: Advanced Solid Tumors

Summary: MGCD516 is a Receptor Tyrosine Kinase (RTK) Inhibitor shown in preclinical models to inhibit a closely related spectrum of RTKs including MET, AXL, MER, and members of the VEGFR, PDGFR, DDR2, TRK and Eph families. In this study, MGCD516 is orally administered to patients with advanced solid tumor malignancies to evaluate its safety, pharmacokinetic, metabolism, pharmacodynamic and clinical activity profiles.

Patients anticipated to be enrolled in Phase 1b will be selected based upon having a tumor type, including but not limited to
- Non-Small Cell Lung Cancer (NSCLC) harboring RET rearrangements
- Any advanced solid tumor with a loss of function mutation in CBL
- Any advanced solid tumor with an amplification of Chromosome 4q12, which harbors the PDGFRA, KIT, and KDR genes
- Any advanced solid tumor with a genetic alteration in AXL

Key Inclusion Criteria:
- Metastatic or unresectable solid tumor malignancy.
- Standard treatment is not available.
- Adequate bone marrow and organ function.

Key Exclusion Criteria:
- History of a significant cardiovascular illness.
- Prolonged corrected QT (QTc) interval.
- Left ventricular ejection fraction < 40%.
- Symptomatic or uncontrolled brain metastases.
- Other active cancer.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02219711