CODEBREAK100 (Amgen)

A Phase 1/2, Study Evaluating the Safety, Tolerability, PK, and Efficacy of AMG 510 in Subjects With Solid Tumors With a Specific KRAS Mutation. This is the trial summary as assessed on clinicaltrials.gov on 09/08/2021.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT03600883

Trial Design:

Arm	Intervention
Experimental: Phase 1 Dose Exploration Part 1 monotherapy	AMG 510 Characterize the pharmacokinetics (PK) of AMG 510 following administration as an oral Tablet formulation
Experimental: Phase 1 Dose Expansion Part 2 monotherapy	AMG 510 Characterize the pharmacokinetics (PK) of AMG 510 following administration as an oral Tablet formulation
Experimental: Phase 2 monotherapy	AMG 510 Characterize the pharmacokinetics (PK) of AMG 510 following administration as an oral Tablet formulation
Experimental: Phase 1 combination arm with AMG 510 and anti PD-1/L1	AMG 510 Characterize the pharmacokinetics (PK) of AMG 510 following administration as an oral Tablet formulation Drug: Anti PD-1/L1 Administered as an intravenous (IV) infusion
Experimental: Phase 1 monotherapy treatment naive advanced NSCLC	AMG 510 Characterize the pharmacokinetics (PK) of AMG 510 following administration as an oral Tablet formulation Midazolam Administered as an oral hydrochloride (HCl) syrup

Experimental: Phase 2 monotherapy dose comparison	AMG 510 Characterize the pharmacokinetics (PK) of AMG 510 following administration as an oral Tablet formulation

Inclusion criteria:

- Men or women greater than or equal to 18 years old.
- Pathologically documented, locally-advanced or metastatic malignancy with, KRAS p.G12C mutation identified through molecular testing.

Exclusion criteria:

- Active brain metastases from non-brain tumors.
- Myocardial infarction within 6 months of study day 1.
- Gastrointestinal (GI) tract disease causing the inability to take oral medication.