

LUN099_Exclusion Criteria

Exclusion:

1. Prior treatment with an agent targeting KRAS G12C (e.g., AMG 510).
2. Active brain metastases. Patients are eligible if brain metastases are adequately treated and patients are neurologically stable (except for residual signs or symptoms related to the central nervous system [CNS] treatment) for at least 2 weeks prior to randomization without the use of corticosteroids or are on a stable or decreasing dose of ≤ 10 mg daily prednisone (or equivalent).
3. Carcinomatous meningitis.
4. Major surgery within 4 weeks prior to randomization.
5. History of intestinal disease or major gastric surgery likely to alter absorption of study treatment or inability to swallow oral medications.
6. Any of the following cardiac abnormalities:
 - a. Unstable angina pectoris or myocardial infarction within the past 6 months.
 - b. Symptomatic or uncontrolled atrial fibrillation within the past 6 months.
 - c. Congestive heart failure \geq NYHA Class 3 within the past 6 months.
 - d. Prolonged QTc interval >480 milliseconds or family or medical history of congenital Long QT Syndrome.
7. History of stroke or transient ischemic attack within 6 months prior to randomization.
8. Ongoing need for treatment with concomitant medication known to cause prolonged QTc interval or known as strong inhibitor or inducer of CYP3A enzyme and that cannot be switched to alternative treatment prior to randomization.
9. Known human immunodeficiency virus (HIV) infection or acute or chronic hepatitis B or C infection. Patients treated for hepatitis C with no detectable viral load and patients treated for HIV with no detectable viral load for at least 1 month while on a stable regimen of agents that are not strong inhibitors of CYP3A4 are permitted.
10. Known or suspected presence of another malignancy that could be mistaken for the malignancy under study during disease assessments.
11. Pregnancy. WOCBP must have a negative serum or urine pregnancy test documented prior to randomization.
12. Breast-feeding or planning to breast-feed during the study or within 6 months after the last dose of study treatment.
13. Any serious illness, uncontrolled inter-current illness, psychiatric illness, active or uncontrolled infection, or other medical history, including laboratory results, which, in the Investigator's opinion, would be likely to interfere with the patient's participation in the study, or with the interpretation of the results.