A Study of ASP3082 in Adults With Advanced Solid Tumors

NCT05382559

Status	RECRUITING
Phase	Phase 1
Sponsor	Astellas Pharma Inc
Enrollment	681 participants

Key Eligibility Criteria

Inclusion (22)

- Participant has locally advanced (unresectable) or metastatic solid tumor malignancy with documented Kirsten rat sarcoma viral oncogene homolog \[KRAS\] G12D mutation and has received prior standard therapy and the investigator does not see any further clinical benefit from continuing such targeted therapy, or is ineligible to receive standard approved therapies (no limit to the number of prior treatment regimens).
- For the ASP3082 monotherapy escalation cohorts, participants with solid tumor malignancies are allowed to be enrolled. Participants with other known KRAS G12 mutations will not be eligible for the study
- For ASP3082 combination therapy with Nab-P+GEM or FOLFIRINOX or NALRIFOX: Participant must have mPDAC that has not been previously treated with chemotherapy. If a participant received (neo)adjuvant therapy, tumor recurrence or disease progression must have occurred at least 6 months after completing the last dose of the (neo)adjuvant therapy.
- Participant consents to provide tumor specimen in a tissue block or unstained serial slides or a tumor biopsy (core needle biopsy or excision) obtained after the last interventional treatment, but prior to start of study intervention. Participant also consents to provide a sample for tumor biopsy during the treatment period as indicated in the study protocol. If a participant cannot provide a fresh tissue biopsy sample, the site should consult with the sponsor/study medical monitor.
- Participant has at least 1 measurable lesion per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.

... and 17 more (see full listing online)

Exclusion (17)

- Participant has received investigational therapy within 21 days or 5 half-lives, whichever is shorter, prior to start of study intervention.
- Participant has symptomatic or untreated central nervous system (CNS) metastases. Participants with asymptomatic, treated CNS metastases are eligible.
- Participant has leptomeningeal disease as a manifestation of the current malignancy.
- Participant has a prior malignancy active (i.e., requiring treatment or intervention) within the previous 2 years, except for local malignancies that have been apparently cured, such as basal or squamous cell skin cancer, superficial bladder cancer or carcinoma in situ of the cervix or breast, which are allowed.
- Participant has a known or suspected hypersensitivity to ASP3082 or any components of the formulation used.

... and 12 more (see full listing online)

Locations (51 total)

City of Hope National Medical Center, Duarte, California, United States
UCLA Santa Monica Hematology Oncology, Santa Monica, California, United States
Denver HealthONE Drug Development Unit, Denver, Colorado, United States
... and 48 more locations