AMG 436 as Monotherapy and Combination Therapy in Participants With MSI-H/dMMR Solid Tumors

NCT07403721

Status	RECRUITING
Phase	Phase 1
Sponsor	Amgen
Enrollment	464 participants

Key Eligibility Criteria

Inclusion (6)

- Age e 18 years (or e legal age within the country if it is older than 18 years).
- Histologically confirmed MSI-H or dMMR metastatic or locally advanced solid tumor by local testing or central testing.
- Tumor tissue (formalin-fixed, paraffin-embedded sample) archival block must be available. Participants without archived tumor tissue may enroll by undergoing tumor biopsy before dosing.
- Disease measurable as defined by Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1).
- Eastern Cooperative Oncology Group performance (ECOG) 0-1.

... and 1 more (see full listing online)

Exclusion (6)

- Participants with primary central nervous system (CNS) tumors.
- Impaired cardiac function or clinically significant cardiac disease.
- Major surgery within 28 days of trial day 1.
- Antitumor therapy (chemotherapy, antibody therapy, molecular targeted therapy, hormonal therapy, or investigational agent) within 21 days of first dose of trial treatment, unless anti-tumor therapy is a therapy with 5 times the half-life being shorter than 21 days (in this case, enrollment may be allowed with washout from prior therapy of \< 21 days.
- Radiation therapy within 28 days of the first dose of trial treatment (or local or focal radiotherapy with palliative intent within 14 days of the first dose).

... and 1 more (see full listing online)

Locations (2 total)

Next Oncology - Dallas, Irving, Texas, United States
Aichi Cancer Center, Nagoya, Aichi-ken, Japan