Research Area:

Non-Small Cell Lung Cancer, Ovarian Cancer, and Other Malignant Solid Tumors

AMG 794

Amgen Protocol Number: 20210007
NCT Number: 05317078

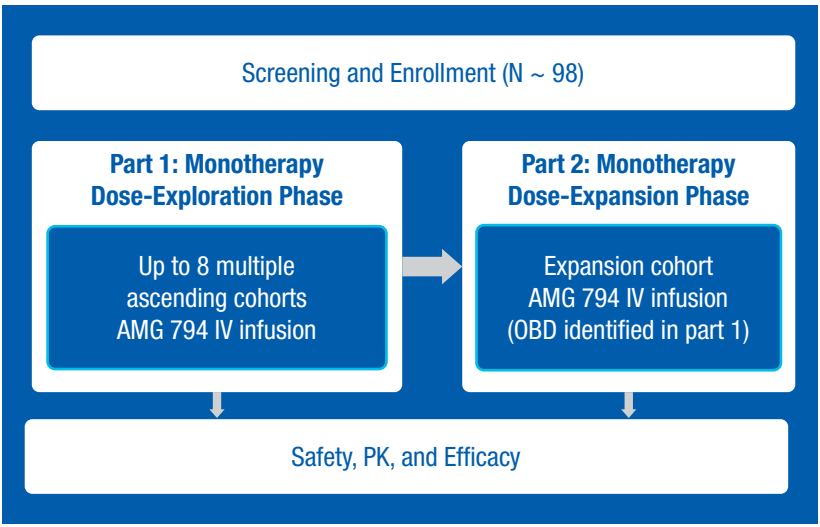
Phase 1, First-in-Human Study to Explore the Safety, Tolerability, and PK of AMG 794 in Patients With Claudin-6–Positive, Advanced/Metastatic NSCLC, Epithelial Ovarian Cancer, and Other Malignant Solid Tumor Indications

Primary Endpoints:

- Patient incidence of DLTs, TEAEs, and TRAEs

Key Secondary Endpoints:

- Minimum efficacious dose
- PK parameters (C_{max}, C_{min}, and AUC)
- Confirmed OR, CA 125 response, DOR, TTP, PFS, and OS



AUC = area under the plasma concentration–time curve; CA 125 = cancer antigen 125; C_{max} = maximum serum concentration; C_{min} = minimum serum concentration; DLT = dose-limiting toxicity; DOR = duration of response; IV = intravenous; NSCLC = non-small cell lung cancer; OBD = optimal biological active dose; OR = objective response; OS = overall survival; PFS = progression-free survival; PK = pharmacokinetic(s); TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event; TTP = time to progression.

Products under investigational study have not been approved by any regulatory authority.

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Key Summary Points:

This is a first-in-human, open-label, phase 1 study evaluating the safety, tolerability, and PK of AMG 794 in patients with CLDN6-positive, advanced/metastatic nonsquamous NSCLC, EOC, and other malignant solid tumor indications.

The study will enroll patients in sequential assignment to determine the OBD at or below the MTD, with MTD 1 as the maximum tolerated starting dose and MTD 2 as the maximum tolerated target dose of AMG 794.

CLDN6 = claudin-6;
CNS = central nervous system;
ECOG = Eastern Cooperative Oncology Group;
EOC = epithelial ovarian cancer;
IHC = immunohistochemistry;
IV = intravenous;
MTD = maximum tolerated dose;
NSCLC = non-small cell lung cancer;
OBD = optimal biological active dose;
PK = pharmacokinetics;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2;
SOC = standard of care;
TNBC = triple-negative breast cancer.

Key Inclusion Criteria:

- Patients ≥ 18 years old with life expectancy > 3 months
- Histologically or cytologically confirmed, metastatic or unresectable, malignant solid tumor diseases expressing CLDN6, including but not limited to NSCLC, EOC, testicular germ cell cancer, uterine endometrial cancer, or TNBC at screening
  - Patients must have exhausted the available SOC systemic therapy or must not be prospects for such therapy
- Positive test result for CLDN6 expression per archival sample or fresh biopsy for enrollment in cohort 3 or higher dose cohort
- Consent to provide archival or fresh tumor tissue for IHC assessment for enrollment in cohort 1 or 2 during dose escalation
  - The enrollment to cohort 1 or 2 is not dependent on the availability of CLDN6 expression test results
- At least one measurable lesion ≥ 10 mm that has not undergone biopsy within 3 months of the screening scan (applicable for dose-expansion cohorts)
- ECOG performance status of 0 to 1

Key Exclusion Criteria:

- History of other malignancy within the past 2 years; evidence of CNS metastases, leptomeningeal disease, or spinal cord compression
- Ongoing or active infection requiring IV anti-infective therapy < 1 week prior to administration of the first dose of study treatment
- History or evidence of SARS-CoV-2 infection, unless agreed upon with the medical monitor
- Major surgery within 4 weeks of administering the first dose of study treatment
- Currently undergoing, or < 4 weeks since ending, treatment with another investigational device or drug study
- Anticancer therapies within 2 weeks or 5 half-lives (whichever is longer) or immunotherapies/monoclonal antibodies within 3 weeks of administering the first dose of study treatment
- Autoimmune disorders requiring chronic systemic steroid therapy or any other immunosuppressive therapy while on study

Additional Information:

- www.clinicaltrials.gov Identifier—NCT05317078
- www.amgentrials.com Protocol Number—20210007

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