Research Area:

# Small Cell Lung Cancer

## AMG 757

Amgen Study ID Number: 20160323 • NCT: 03319940

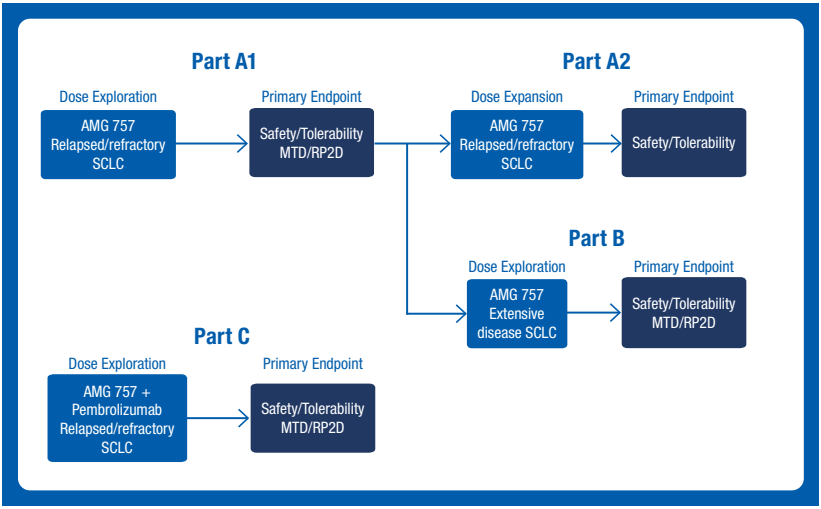
### A Phase 1 Study Evaluating the Safety, Tolerability and Pharmacokinetics of AMG 757 in Patients With Small Cell Lung Cancer

**Primary Endpoints:**

- Dose-limiting toxicities (DLTs)
- Treatment-emergent adverse events (TEAEs)
- Treatment-related adverse events (TRAEs)

**Key Secondary Endpoints:**

- Overall response rate (ORR) per RECIST v1.1
- Duration of response (DOR)
- Progression-free survival (PFS) and Overall survival (OS)
- Pharmacokinetics




MTD, maximum tolerated dose; RECIST, response evaluation criteria in solid tumors; RP2D, recommended phase 2 dose; SCLC, small cell lung cancer.



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## Key Summary Points:

This is an open-label, ascending, multiple dose, phase 1 study evaluating AMG 757 as monotherapy and in combination with anti-PD1 therapy. AMG 757 will be administered as a short term intravenous (IV) infusion every 2 weeks (with or without step dosing) in subjects with SCLC.

The dose exploration phase of the study will estimate the maximum tolerated dose (MTD) or Recommended Phase 2 Dose (RP2D) of AMG 757 either as monotherapy or in combination with anti-PD1 therapy.

## Additional Information:

- www.clinicaltrials.gov Identifier-NCT03319940
- www.amgentrials.com Protocol Number-20160323

ECOG, Eastern Cooperative Oncology Group
ED, extensive disease
PD1, programmed cell death protein 1
RR, relapsed or refractory
SCLC, small cell lung cancer
TRAE, treatment-related adverse event

## Key Inclusion Criteria:

- Age ≥ 18 years old
- Histologically or cytologically confirmed SCLC
  - **Part A and Part C**: RR SCLC who progressed or recurred following platinum-based chemotherapy
  - **Part B**: ED SCLC with ongoing clinical benefit following no more than 6 cycles of first-line platinum-based chemotherapy with last dose of chemotherapy ≥ 28 days prior to the study day 1
- ECOG performance status of 0-2

## Key Exclusion Criteria:

- History of other malignancy within past 2 years prior to first dose of AMG 757 with exceptions
- Untreated or symptomatic brain metastases and leptomeningeal disease
- Prior anti-cancer therapy: at least 28 days must have elapsed between any prior anti-cancer therapy and first dose of AMG 757
  Exceptions:
  - At least 14 days since chemotherapy and all TRAE has resolved to ≤ Grade 1
  - Completion of prior palliative radiotherapy at least 7 days prior to first AMG 757 dose
- Patients who experienced severe, life-threatening or recurrent (Grade ≥ 2) immune-mediated adverse events, or infusion-related reactions from immune-oncology therapy
- Evidence of interstitial lung disease or active non-infectious pneumonitis
- Diagnosis of immunodeficiency or receiving systemic steroid therapy or immunosuppressive therapy within 7 days of first AMG 757 dose
- Part C: History of solid organ transplant or active autoimmune disease requiring systemic treatment within past 2 years

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