Dimensions: 5.50 x 8.50 inches

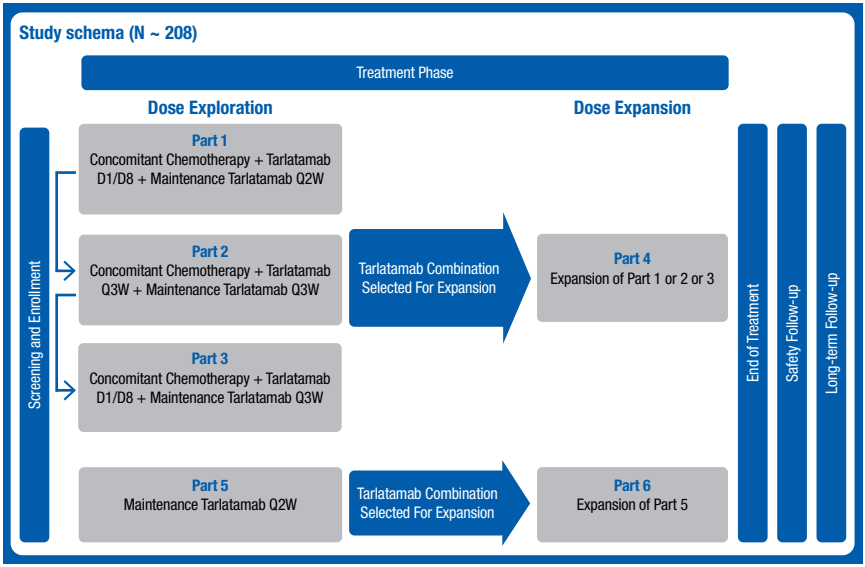
Research Area:

Small Cell Lung Cancer

Tarlatamab (AMG 757)

Amgen Study ID Number: 20200469
NCT Number: 05361395
EudraCT Number: 2021-005462-17

A Phase 1b Study Evaluating the Safety and Efficacy of First-line Tarlatamab in Combination With Carboplatin, Etoposide, and PD-L1 Inhibitor in Patients With Extensive-Stage Small Cell Lung Cancer (DeLLphi-303)



Primary Endpoints:

- Incidence of DLTs
- Incidence of TEAEs and TRAEs
- Incidence of clinically significant changes in vital signs, ECG measurements, and clinical laboratory tests

Secondary Endpoints:

- PFS (6-month)
- OR
- DOR
- DCR
- OS
- Serum concentration of tarlatamab

D, day; DCR, disease control rate; DLT, dose-limiting toxicity; DOR, duration of response; ECG, electrocardiogram; OR, objective response; OS, overall survival; PD-L1, programmed death ligand; PFS, progression-free survival; Q2W, every 2 weeks; Q3W, every 3 weeks; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

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

AMGEN®
Oncology

Tarlatamab (AMG 757)

Key Summary Points:

This is a phase 1b study evaluating the safety and efficacy of first-line tarlatamab in combination with carboplatin, etoposide, and PD-L1 inhibitor in patients with extensive-stage small cell lung cancer.

Key Inclusion Criteria:

- Age ≥ 18 years old
- Histologically or cytologically confirmed ES-SCLC and no prior systemic treatment for ES-SCLC
- ECOG performance status of 0–1
- Adequate organ function as defined in protocol
- Patients with treated asymptomatic brain metastases are eligible provided they meet defined criteria

Key Exclusion Criteria:

- History of other malignancy within the past 2 years with exceptions
- Major surgery within 28 days of study day 1
- Untreated or symptomatic brain metastases and leptomeningeal disease
- Recurrent grade 2 pneumonitis or severe or life-threatening immune-mediated adverse events or infusion-related reactions
- History of immune-related colitis, hypophysitis, or pituitary dysfunction
- Evidence of interstitial lung disease or active, non infectious pneumonitis
- Diagnosis of immunodeficiency or receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study treatment
- History of solid organ transplantation
- Active autoimmune disease that has required systemic treatment (except replacement therapy) within the past 2 years or any other diseases requiring immunosuppressive therapy while on study. Participants with type I diabetes, vitiligo, psoriasis, or hypo- or hyperthyroidism not requiring immunosuppressive treatment are permitted

Additional Information:

- www.clinicaltrials.gov Identifier – NCT05361395
- www.amgentrials.com Protocol Number – 20200469
- www.clinicaltrialsregister.eu EudraCT Number – 2021 – 005462 – 17

ECOG, Eastern Cooperative Oncology Group; ES-SCLC, extensive-stage small cell lung cancer; PD-L1, programmed death ligand.

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

AMGEN®

Oncology

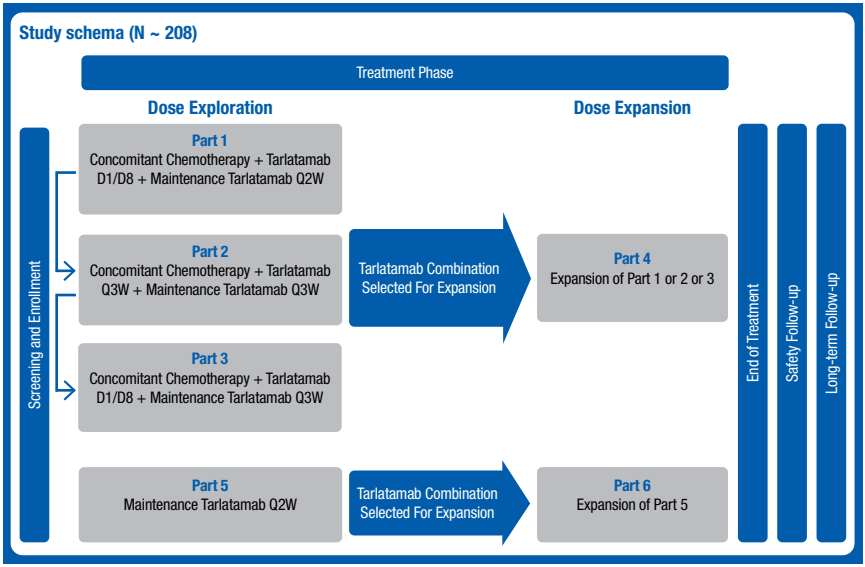
Research Area:

Small Cell Lung Cancer

Tarlatamab (AMG 757)

Amgen Study ID Number: 20200469
NCT Number: 05361395
EudraCT Number: 2021-005462-17

A Phase 1b Study Evaluating the Safety and Efficacy of First-line Tarlatamab in Combination With Carboplatin, Etoposide, and PD-L1 Inhibitor in Patients With Extensive-Stage Small Cell Lung Cancer (DeLLphi-303)



Primary Endpoints:

- Incidence of DLTs
- Incidence of TEAEs and TRAEs
- Incidence of clinically significant changes in vital signs, ECG measurements, and clinical laboratory tests

Secondary Endpoints:

- PFS (6-month)
- OR
- DOR
- DCR
- OS
- Serum concentration of tarlatamab

D, day; DCR, disease control rate; DLT, dose-limiting toxicity; DOR, duration of response; ECG, electrocardiogram; OR, objective response; OS, overall survival; PD-L1, programmed death ligand; PFS, progression-free survival; Q2W, every 2 weeks; Q3W, every 3 weeks; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

AMGEN®
Oncology

Tarlatamab (AMG 757)

Key Summary Points:

This is a phase 1b study evaluating the safety and efficacy of first-line tarlatamab in combination with carboplatin, etoposide, and PD-L1 inhibitor in patients with extensive-stage small cell lung cancer.

Key Inclusion Criteria:

- Age ≥ 18 years old
- Histologically or cytologically confirmed ES-SCLC and no prior systemic treatment for ES-SCLC
- ECOG performance status of 0–1
- Adequate organ function as defined in protocol
- Patients with treated asymptomatic brain metastases are eligible provided they meet defined criteria

Key Exclusion Criteria:

- History of other malignancy within the past 2 years with exceptions
- Major surgery within 28 days of study day 1
- Untreated or symptomatic brain metastases and leptomeningeal disease
- Recurrent grade 2 pneumonitis or severe or life-threatening immune-mediated adverse events or infusion-related reactions
- History of immune-related colitis, hypophysitis, or pituitary dysfunction
- Evidence of interstitial lung disease or active, non infectious pneumonitis
- Diagnosis of immunodeficiency or receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study treatment
- History of solid organ transplantation
- Active autoimmune disease that has required systemic treatment (except replacement therapy) within the past 2 years or any other diseases requiring immunosuppressive therapy while on study. Participants with type I diabetes, vitiligo, psoriasis, or hypo- or hyperthyroidism not requiring immunosuppressive treatment are permitted

Additional Information:

- www.clinicaltrials.gov Identifier – NCT05361395
- www.amgentrials.com Protocol Number – 20200469
- www.clinicaltrialsregister.eu EudraCT Number – 2021 – 005462 – 17

ECOG, Eastern Cooperative Oncology Group; ES-SCLC, extensive-stage small cell lung cancer; PD-L1, programmed death ligand.

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

AMGEN®

Oncology