Research Area:

Small Cell Lung Cancer

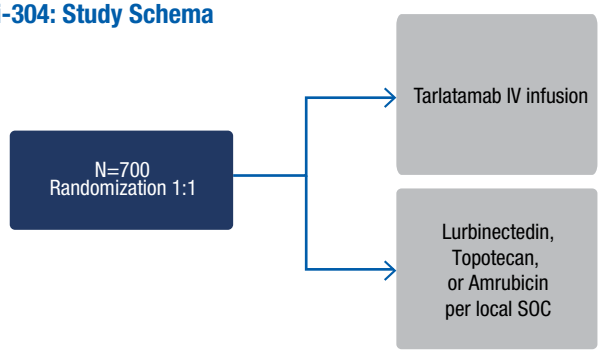
DeLLphi 304

Tarlatamab

Amgen Study ID Number: 20210004
NCT Number: NCT05740566

DeLLphi-304 Study: A Randomized, Open-label, Phase 3 Study of Tarlatamab Compared With Standard of Care in Subjects With Relapsed Small Cell Lung Cancer After Platinum-based First-line Chemotherapy

DeLLphi-304: Study Schema



Primary Endpoint:

- OS

Key Secondary Endpoints:

- PFS
- Change from baseline in selected functional scales and disease symptom items included in cancer QoL questionnaire
- Change from baseline in selected disease symptoms included in lung cancer QoL questionnaire
- OR
- DC
- DOR
- OS
- Incidence of TEAEs
- Serum concentrations of tarlatamab
- Number of participants who experience anti-tarlatamab antibodies

DC, disease control; DOR, duration of response; IV, intravenous; N, number of subjects; OR, overall response; OS, overall survival; PFS, progression-free survival; QoL, quality of life; SOC, standard of care; TEAE, treatment-emergent adverse event.

AMGEN

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

Tarlatamab

Key Summary Points:

DeLLphi-304 Study: This is a randomized, open-label, phase 3 study evaluating the efficacy, safety, tolerability, and pharmacokinetics of tarlatamab compared with SOC in subjects with relapsed SCLC after platinum-based first-line chemotherapy

Key Inclusion Criteria:

- Age ≥ 18 years
- Histologically or cytologically confirmed R/R SCLC
- Progression or recurrence after one platinum-based chemotherapy regimen
- Provision of evaluable tumor sample for central testing
- Measurable disease (per RECIST v1.1) within the 21-day screening period
- ECOG performance status of 0 or 1
- Life expectancy ≥ 12 weeks
- Adequate organ function

Key Exclusion Criteria:

- Untreated or symptomatic CNS metastases with exceptions defined in study protocol
- Prior therapy with tarlatamab or any of the standard of care chemotherapy included as part of this trial
- Prior therapy with any selective inhibitor of the DLL3 pathway
- Participant received more than one prior systemic therapy regimen for SCLC
- Diagnosis or evidence of leptomeningeal disease
- Prior history of immune checkpoint inhibitors resulting in safety events defined in the study protocol
- Other medical conditions: active autoimmune disease; history of solid organ transplantation; other malignancies; HIV and hepatitis infection; evidence of interstitial lung disease or active, non-infectious pneumonitis

Additional Information:

- www.clinicaltrials.gov Indentifier – NCT05740566
- www.amgentrials.com Protocol Number – 20210004

CNS, central nervous system; DLL3, delta-like ligand 3; ECOG, Eastern Cooperative Oncology Group; HIV, human immunodeficiency virus; R/R, relapsed or refractory; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer; SOC, standard of care.

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