Research Area:

Extensive-Stage Small Cell Lung Cancer

DeLLphi 305

Tarlatamab

Amgen Study ID Number: 20200041
NCT Number: NCT06211036

DeLLphi-305 Study: A Phase 3, Randomized, Open-label, Multicenter Study of Tarlatamab With Durvalumab vs Durvalumab Alone in First-line Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Following Platinum, Etoposide, and Durvalumab

Primary Endpoint:

- OS

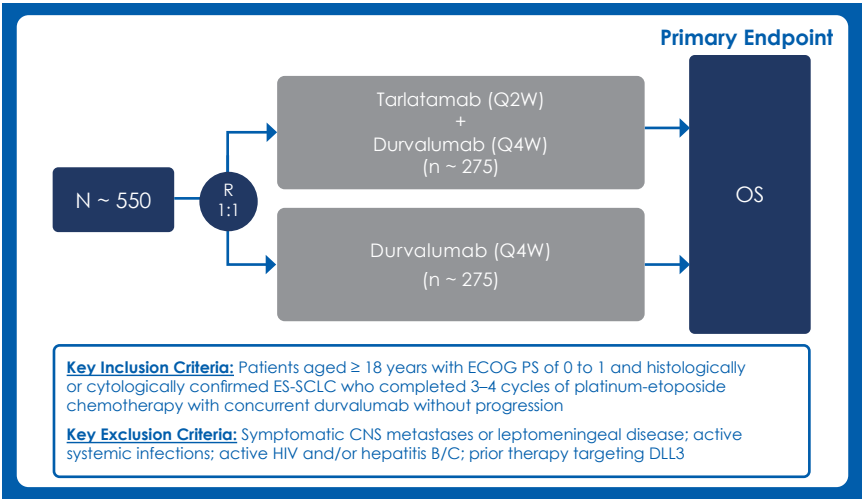
Key Secondary Endpoint:

- PFS

Other Secondary Endpoints:

- PFS*
- OS†
- ORR
- DCR
- DoR
- TTP
- PRO/QoL
- Number of participants with TEAEs
- Serum concentrations of tarlatamab
- Incidence of anti-tarlatamab antibody formation

DeLLphi-305: Study Schema



Key Inclusion Criteria: Patients aged ≥ 18 years with ECOG PS of 0 to 1 and histologically or cytologically confirmed ES-SCLC who completed 3–4 cycles of platinum-etoposide chemotherapy with concurrent durvalumab without progression

Key Exclusion Criteria: Symptomatic CNS metastases or leptomeningeal disease; active systemic infections; active HIV and/or hepatitis B/C; prior therapy targeting DLL3

*PFS at 6 months, 1 year, and 2 years. †OS at 6 months, 1 year, 2 years, and 3 years.
CNS, central nervous system; DCR, disease control rate; DLL3, delta-like ligand 3; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ES-SCLC, extensive-stage small cell lung cancer; HIV, human immunodeficiency virus; N, total number of participants; n, number of participants; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PRO, patient-reported outcome; Q2W, every 2 weeks; Q4W, every 4 weeks; QoL, quality of life; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; TEAE, treatment-emergent adverse event; TTP, time to progression.

AMGEN

Tarlatamab

Key Summary Point:

DeLLphi-305 Study:
This is a randomized, open-label, multicenter, phase 3 study designed to evaluate the efficacy and safety of tarlatamab in combination with durvalumab compared with durvalumab alone in first-line ES-SCLC following platinum, etoposide, and durvalumab

Inclusion Criteria:

- Age ≥ 18 years
- Histologically or cytologically documented ES-SCLC
- Completed 3–4 cycles of platinum-etoposide chemotherapy with concurrent durvalumab as first-line treatment of ES-SCLC prior to enrollment, without progression per RECIST 1.1
- ECOG PS of 0 to 1
- Minimum life expectancy > 12 weeks
- Adequate organ function
- Toxicities attributed to prior anticancer therapy resolved to grade ≤ 1, unless otherwise specified; excludes alopecia or fatigue

Exclusion Criteria:

- Evidence of symptomatic CNS metastases or leptomeningeal disease
- Received systemic corticosteroids or any other immunosuppressive therapy within 14 days prior to start of study treatment
- Major surgical procedures within 28 days prior to start of study treatment
- Prior history of severe or life-threatening events from any immune-mediated therapy
- History of other malignancy within the past 2 years (contact investigator for exceptions); history of solid organ transplantation; MI and/or symptomatic CHF (NYHA > Class II), or history of arterial thrombosis, within 6 months of study start
- Active or prior documented autoimmune or inflammatory disorders
- Active HIV and/or hepatitis B and/or C infection
- Prior therapy with any selective inhibitor of the DLL3 pathway

Additional Information:

- www.clinicaltrials.gov
  Identifier – NCT06211036
- www.amgentrials.com
  Protocol Number – 20200041

CHF, congestive heart failure; CNS, central nervous system; DLL3, delta-like ligand 3; ECOG PS, Eastern Cooperative Oncology Group performance status; ES-SCLC, extensive-stage small cell lung cancer; HIV, human immunodeficiency virus; MI, myocardial infarction; NYHA, New York Heart Association; RECIST, Response Evaluation Criteria in Solid Tumors.

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