NEW CLINICAL TRIAL OPEN FOR INCLUSION

PROTOCOL TITLE

A Phase 1b Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Tarlatamab in Combination with ZL-1310 with or without anti-PD-L1 in Participants with Small Cell Lung Cancer

ALIAS	CTO NUMBER	SPONSOR
DeLLphi - 313	CTO25073AMG	AMGEN

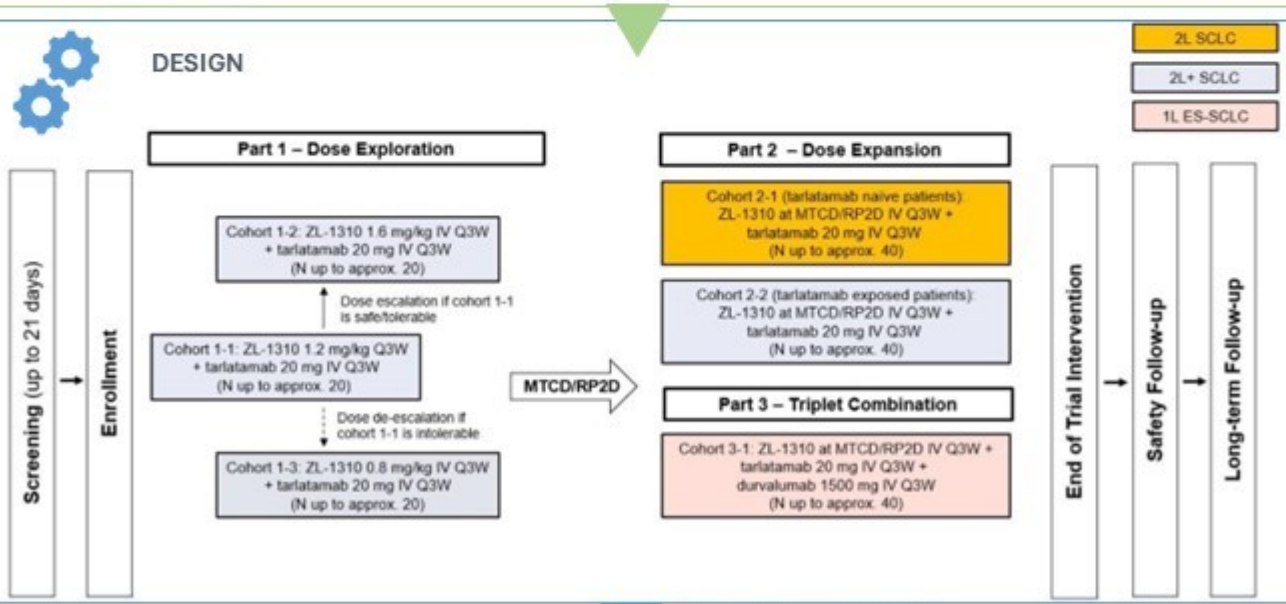
KEY INCLUSION CRITERIA

- Histologically or cytologically confirmed SCLC
- Part 1: SCLC that has progressed or recurred following at least 1 line of platinum-based anti-cancer therapy
- Part 2: Previously treated SCLC meeting following criteria:
  - Cohort 2-1: SCLC that has progressed or recurred following one line of platinum-based anti-cancer therapy. No prior tarlatamab is allowed.
  - Cohort 2-2: SCLC that has progressed or recurred following at least one line of platinum-based anti-cancer therapy. Participants must have received previous tarlatamab.
- For Part 3, participants must have ES-SCLC and no prior systemic treatment for ES-SCLC other than 1 cycle of platinum-based anti-cancer therapy.
- Adequate organ function & ECOG 0-1
- At least 1 measurable lesion as defined per RECIST v1.1 within 21-day screening period, not previously irradiated

KEY EXCLUSION CRITERIA

- Symptomatic CNS metastases or evidence of leptomeningeal disease
- Spinal cord compression requiring local intervention
- Previous use tarlatamab or DLL3-directed therapy (nvt voor cohort 2-2)
- Active autoimmune disease that has required systemic treatment greater than prednisone 10 mg or equivalent steroid dose (except replacement therapy) within the past 2 years or any other diseases requiring immunosuppressive therapy or disease modifying agents while on study.
- Receiving systemic corticosteroid therapy or any other form of systemic immunosuppressive therapy within 7 days prior to first dose of trial intervention (low dose permitted
- History of ILD/pneumonitis or thoracic radiation therapy within 90d prior to first dose of trial intervention
- Prior exposure to topoisomerase I inhibitors or ADC with topoisomerase I inhibitor payload
- Receiving strong CYP3A4 or CYP2D6 inhibitors within 14 days or 5 half-lifes before the first dose of study treatment

DESIGN



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