Study Comparing Tarlatamab and Durvalumab Versus Durvalumab Alone in First-Line Extensive-Stage Small-Cell Lung Cancer (ES-SCLC) Following Platinum, Etoposide and Durvalumab

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 99 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion: * Participant has provided informed consent prior to initiation of any study specific activities/procedures. * Age \>= 18 years (or \>= legal adult age within the country if it is older than 18 years). * Completed 3-4 cycles of platinum-etoposide chemotherapy with concurrent durvalumab as first-line treatment of extensive-stage (ES)-SCLC prior to enrollment, without disease progression (ongoing response or stable disease) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1). * Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 to 1. * Minimum life expectancy \> 12 weeks. * Toxicities attributed to prior anti-cancer therapy resolved to grade ≤ 1, unless otherwise specified, excluding alopecia or fatigue. * Adequate organ function. * Histologically or cytologically documented extensive-stage disease (American Joint Committee on Cancer, 2017, IV small-cell lung cancer (SCLC) \[T any, N any, M1 a/b/c\]), or T3 to T4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan. Participants with prior limited-stage (LS)-SCLC are allowed if the interval is \> 6 months since the end of previous therapy and progression, in discussion with the medical monitor. Exclusion * Symptomatic central nervous system (CNS) metastases, or leptomeningeal disease. Participants with treated brain metastases are eligible as per protocol. * Prior history of severe or life-threatening events from any immune-mediated therapy. * History of other malignancy within the past 2 years, with some exceptions as per protocol. * Active or prior documented autoimmune or inflammatory disorders as per protocol. * Myocardial infarction and/or symptomatic congestive heart failure (New York Heart Association \> class II) within 6 months of first dose of study treatment. * History of arterial thrombosis (e.g., stroke or transient ischemic attack) within 6 months of first dose of study treatment. * Evidence of interstitial lung disease (ILD) or active, non-infectious pneumonitis. * History of solid organ transplant. * Major surgical procedures within 28 days of first dose of study treatment. * Known human immunodeficiency virus (HIV) infection (participants with HIV infection on antiviral therapy and undetectable viral load are permitted with a requirement for regular monitoring for reactivation for the duration of treatment on study), hepatitis C infection (participants with hepatitis C that achieve a sustained virologic response after antiviral therapy are allowed), or hepatitis B infection (participants with hepatitis B surface antigen \[HBsAg\] or core antibody that achieve sustained virologic response with antiviral therapy are permitted with a requirement for regular monitoring for reactivation for the duration of treatment on the study). * Receiving systemic corticosteroid therapy or any other form of immunosuppressive therapy within 14 days prior to first dose of study treatment. * History of allergic reactions or acute hypersensitivity reaction to antibody therapies, platinum chemotherapy, or etoposide. * Participant with symptoms and/or clinical signs and/or radiographic signs that indicate an acute and/or uncontrolled active systemic infection within 7 days prior to the first dose of study treatment. * Participant has known active infection requiring parenteral antibiotic treatment. Upon completion of parenteral antibiotics and resolution of symptoms, the participant may be considered eligible for the study from an infection standpoint. * Treatment with live virus, including live-attenuated vaccination, within 4 weeks prior to the first dose of study treatment. Inactive vaccines (e.g., non-live or non-replicating agent) and live viral non-replicating vaccines (e.g., Jynneos for Monkeypox infection) within 30 days prior to first dose of study treatment. * Prior therapy with any selective inhibitor of the delta-like ligand 3 (DLL3) pathway. * Receiving another anti-cancer therapy. Adjuvant hormonal therapy for resected breast cancer is permitted. * Treatment in an alternative investigational trial within 28 days prior to enrollment. * Has received or is planning to receive consolidative chest radiation for extensive stage disease. * Female participants of childbearing potential unwilling to use protocol specified method of contraception during treatment as per protocol. * Female participants who are breastfeeding or who plan to breastfeed while on study as per protocol. * Female participants planning to become pregnant or donate eggs while on study as per protocol. * Female participants of childbearing potential with a positive pregnancy test assessed at screening by a highly sensitive serum pregnancy test. * Male participants with a female partner of childbearing potential who are unwilling to practice sexual abstinence (refrain from heterosexual intercourse) or use contraception during treatment as per protocol. * Male participants with a pregnant partner who are unwilling to practice abstinence or use a condom during treatment as per protocol. * Male participants unwilling to abstain from donating sperm during treatment as per protocol. * Participant has known sensitivity to any of the products or components to be administered during dosing. * Participant has known sensitivity to any of the products or components to be administered during dosing. * History or evidence of any other clinically significant disorder, condition or disease that, in the opinion of the investigator or physician if consulted, would pose a risk to participant safety or interfere with the study evaluation, procedures, or completion. * Participant likely to not be available to complete all protocol-required study visits or procedures, and/or to comply with all required study procedures (eg, Clinical Outcome Assessments) to the best of the participant and investigator's knowledge. Participants who are unable to complete clinical outcome assessments are eligible.

Conditions & Interventions

Interventions:

DRUG: Tarlatamab, DRUG: Durvalumab

Conditions:

Extensive-Stage Small-Cell Lung Cancer, Small-Cell Lung Cancer

Keywords:

Extensive-Stage Small-Cell Lung Cancer, ES-SCLC, Platinum, Etoposide, Durvalumab, Tarlatamab, AMG 757

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

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