Safety and Efficacy of BNT327, an Investigational Therapy in Combination With Chemotherapy for Patients With Untreated Small-cell Lung Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Have histologically or cytologically confirmed ES-SCLC (using the AJCC \[American Joint Committee on Cancer\] tumor node metastasis staging system combined with Veterans Administration Lung Study Group \[VALG\]'s two stage classification scheme). For AJCC tumor node metastasis staging system: AJCC 8th edition stage IV (T any, N any, M1a/b/c), or T3\~4 for multiple lung nodules or tumor/nodule volume that cannot be encompassed in a tolerable radiotherapy plan. * Have not had prior systemic therapy for ES-SCLC. However, participants with prior chemoradiotherapy for limited-stage-SCLC must have been treated with curative intent and had a treatment-free interval of at least 6 months after the last chemotherapy, radiotherapy, or chemoradiotherapy before diagnosis of ES-SCLC to be eligible. * Have at least one measurable lesion as the targeted lesion based on RECIST v1.1. Lesions treated after prior local treatment (radiotherapy, ablation, interventional procedures, etc.) are generally not considered as target lesions. If the lesion with prior local treatment is the only targeted lesion, evidence-based radiology must be provided to demonstrate disease progression (the single bone metastasis or the single central nervous system metastasis should not be considered as a measurable lesion). * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. * Adequate hematologic and organ function as defined in the protocol.

Exclusion Criteria:

* Have histologically or cytologically confirmed SCLC with combined histologies. * Have received any of the following therapies or drugs within the noted time intervals prior to study treatment: * Within 2 weeks: small molecule agents with half-life of \<7 days; radiation outside the thoracic cavity including whole brain radiation. Of note, other local radiation for brain lesions (not whole brain) is allowed; local radiation for bone lesions is allowed. Palliative bone radiation or brain stereotactic radiosurgery would not require a washout period, but participants should recover from radiotherapy-related toxicity. * Within 4 weeks: radiation involving the thoracic cavity; small molecule targeted agents with half-life of ≥7 days; monoclonal antibodies, antibody-drug conjugates, radioimmunoconjugates, or T-cell or other cell-based therapies. * Have received prior treatment with anti-vascular endothelial growth factor (VEGF) monoclonal antibody, or programmed death (ligand)-1 (PD\[L\]-1)/VEGF bispecific antibody. * Have received systemic corticosteroids (at a dosage greater than 10 mg/day of prednisone or an equivalent dose of other corticosteroids) within 7 days prior to the initiation of study treatment. Note: local, intranasal, intraocular, intra-articular or inhaled corticosteroids, short-term use (≤7 days) of corticosteroids for prophylaxis (e.g., prevention of contrast agent allergy) or treatment of non-autoimmune conditions (e.g., delayed hypersensitivity reactions caused by exposure to allergens) are allowed. * Have the following central nervous system metastases: * Participants with untreated brain metastases that are symptomatic or large (e.g., greater than 2 cm). * Participants with treated central nervous system (CNS) metastases who are not neurologically stable or on steroids (at a dosage greater than 10 mg/Day of prednisone or an equivalent dose of other corticosteroid) within 7 days before initiating study treatment of this study. * Participants with known leptomeningeal metastases. * Have uncontrolled hypertension or poorly controlled diabetes prior to study treatment. * Have a serious or non-healing wound, or (incompletely healed) bone fracture. This includes history of abdominal fistula, tracheoesophageal fistula, gastrointestinal perforation, or intra-abdominal abscess for which an interval of 6 months must pass before study entry. In addition, the participant must have undergone correction (or spontaneous healing) of the perforation/fistula and/or the underlying process causing the fistula/perforation. * Have a significant risk of hemorrhage (per investigator clinical judgment) as defined in the protocol. * Have superior vena cava syndrome or symptoms of spinal cord compression that requires urgent medical intervention. NOTE: Other protocol defined Inclusion/Exclusion criteria apply.

Conditions & Interventions

Interventions:
DRUG: Pumitamig, DRUG: Atezolizumab, DRUG: Etoposide, DRUG: Carboplatin (or cisplatin if carboplatin is not tolerated)
Conditions:
Extensive-Stage Small-Cell Lung Cancer
Keywords:
First-line ES-SCLC, SCLC, Immunotherapy in combination with chemotherapy, Untreated, Bispecific antibody, Programmed death-ligand 1 (PD-L1), Vascular endothelial growth factor (VEGF) A, Immunotherapy, Combination with other investigational agents, Pumitamig, BNT327, Check point inhibitor, Lung cancer, Etoposide, Carboplatin, Cisplatin

More Information

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