TPS8127 **Poster Session**

The TIGOS trial: A randomized, double-blind phase 3 trial of atigotatug + nivolumab fixed-dose combination with chemotherapy vs atezolizumab with chemotherapy in patients with 1L extensive-stage small cell lung cancer (ES-SCLC).

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Background: Atigotatug is an innate immune inducer monoclonal antibody that binds fucosyl-monosialoganglioside-1 (fuc-GM1) with high affinity and specificity, thereby inducing immune-mediated tumor cell death. Fuc-GM1, a cell surface target, is expressed in 50%–90% of SCLC tumors. In a randomized, open-label phase 2 study, atigotatug combined with nivolumab and chemotherapy vs nivolumab and chemotherapy alone has shown a promising trend in overall survival (OS) with median OS of 15.6 mo vs 11.4 mo, respectively (HR 0.71; 95% CI 0.44–1.16), as a first-line treatment in ES-SCLC. Based on these results, a confirmatory trial comparing this regimen to the standard of care is warranted. TIGOS (NCT06646276) is a randomized, double-blind, multicenter phase 3 trial to compare the efficacy and safety of atigotatug + nivolumab fixed-dose combination with chemotherapy vs atezolizumab with chemotherapy. **Methods:** Approximately 530 eligible patients will be randomized 1:1 to receive either atigotatug + nivolumab fixed-dose combination with carboplatin and etoposide Q3W (induction) followed by atigotatug + nivolumab fixed dose combination (maintenance) Q4W or atezolizumab with carboplatin and etoposide Q3W (induction) followed by atezolizumab (maintenance) Q4W. Patients will be stratified by ECOG performance status (PS) 0–1, presence of liver metastases, and presence of brain metastases at baseline. Treatment will continue until disease progression, unacceptable toxicity, death, or withdrawal of consent. Eligible patients must be ≥18 years old, have histologically or cytologically documented SCLC, ≥1 measurable lesion outside the central nervous system (CNS), any previous limited-stage SCLC treatment completed ≥6 months prior to study treatment initiation, and an ECOG PS of 0–1. Key exclusion criteria include prior treatment for ES-SCLC, untreated symptomatic CNS metastases, and prior treatment targeting T-cell co-stimulation, checkpoint pathways, and/or fuc-GM1. The primary endpoint is OS, and the secondary endpoints are time to definitive deterioration, safety, objective response, duration of response, and progression-free survival, as assessed by the investigator. Assessment of pre- and on-treatment changes in biomarkers will be part of an exploratory analysis. This study will be conducted in 180 locations, with a primary completion date expected in April 2028. Clinical trial information: NCT06646276. Research Sponsor: Bristol Myers Squibb.