TPS8124 **Poster Session**

TIGOS-LS, an open-label, randomized study of BMS-986489 vs durvalumab as consolidation therapy following chemoradiotherapy in limited-stage small-cell lung cancer.

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Background: Standard treatment for limited-stage small-cell lung cancer (LS-SCLC) has recently changed to add durvalumab consolidation after concurrent chemoradiotherapy. Although durvalumab consolidation increases overall survival (OS; Cheng et al. 2024), other therapeutic agents may be able to provide further improvement. BMS-986489 is a potential first-in-class fixed-dose combination of atigotatug (BMS-986012) and nivolumab. Atigotatug binds to fucosyl-monosialoganglioside-1 (fuc-GM1), which is highly expressed on SCLC cells and is largely absent in normal tissues. This binding results in tumor cell death by antibody-dependent cellular cytotoxicity, antibody-dependent cellular phagocytosis, or complement-dependent cytotoxicity. The immune effects initiated by atigotatug may further enhance T cell activation by nivolumab, thereby improving outcomes after chemoradiotherapy. In a randomized phase II study in extensive-stage SCLC, atigotatug improved median OS when added to carboplatin, etoposide, and nivolumab (CE/NIVO): 15.6 months (95% confidence interval [CI]: 11.3-NE) vs 11.4 months (95% CI: 9.3-16.5) with CE/NIVO alone (Kalinka et al. 2024). **Methods:** TIGOS-LS is an open-label, randomized study to evaluate the safety and efficacy of BMS-986489 as consolidation therapy vs the new standard durvalumab following chemoradiotherapy in LS-SCLC. Approximately 250 participants will be enrolled at 80 sites within the US. Eligible participants will be adults (≥18 years) with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and histologically or cytologically confirmed LS-SCLC. All participants must have completed concurrent chemoradiotherapy for LS-SCLC without progression; prophylactic cranial irradiation (PCI) will be permitted before initiation of study treatment. Confirmation of fuc-GM1 expression will not be required. Participants will be stratified based on disease stage (I/II vs III) and receipt of PCI and will be randomly allocated in a 1:1 ratio to either the BMS-986489 or durvalumab arms. BMS-986489 or durvalumab will be administered intravenously at a fixed dose once every 4 weeks for up to 2 years or until other discontinuation criteria are met. Response will be evaluated by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Survival follow-up will occur every 12 weeks for up to 3 years. The primary endpoint is OS. Key secondary endpoints include progression-free survival, objective response rate, clinical benefit rate, disease control rate, duration of response, and safety parameters. Enrollment is projected to start in April 2025. Clinical trial information: NCT06773910. Research Sponsor: Bristol Myers Squibb.