TPS4208 **Poster Session**

A phase II study of sacituzumab govitecan for advanced esophageal squamous cell carcinoma patients (SG-ESCC).

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Background: Esophageal squamous cell carcinoma (ESCC) remains a significant global health challenge, particularly in Asia. There are limited treatment options for advanced ESCC patients who fail platinum-based chemotherapy and anti-PD-1/PD-L1 therapy, resulting in poor prognoses. Trophoblast cell surface antigen 2 (Trop-2), a transmembrane protein overexpressed in ESCC, offers a potential therapeutic target due to its differential expression between tumors and normal tissues. Sacituzumab govitecan, an antibody-drug conjugate (ADC) comprising an anti-Trop-2 antibody linked to a topoisomerase I inhibitor payload, has shown efficacy in triple-negative and hormone receptor-positive breast cancers. This study aims to investigate the efficacy and safety of sacituzumab govitecan in patients with advanced ESCC.
Methods: This investigator-initiated, prospective, phase II, single-arm, multi-center trial evaluates the efficacy and safety of sacituzumab govitecan (10 mg/kg IV on days 1 and 8 of a 21-day cycle) in advanced ESCC patients. Eligible patients must have failed prior platinum-based chemotherapy and anti-PD-1/PD-L1 therapy, exhibit measurable disease per RECIST 1.1, and have an ECOG performance status ≤1. The primary endpoint is the objective response rate (ORR) by RECIST 1.1. Secondary endpoints include overall survival, progression-free survival, duration of response, and safety outcomes. Biomarker analyses will explore Trop-2 expression and other molecular markers associated with treatment efficacy and resistance as well as toxicity. A total of 35 patients will be enrolled employing Simon's two-stage design, with a type I error rate of 0.1 and 80% power to detect an ORR ≥25%, considered promising compared to the historical control of ≤10%. In the first stage, 16 patients will be accrued, with ≥2 responses required to proceed to the second stage of 15 additional patients. Accounting for an anticipated 10% dropout rate, the study aims to complete enrollment within 24 months. Enrollment began in August 2024, and as of December 2024, 5 of the planned 35 patients have been enrolled. Clinical trial information: NCT06329869. Research Sponsor: Gilead Sciences.