TPS8120 **Poster Session**

Neotrace: A multicenter phase II study of neoadjuvant sacituzumab govitecan plus zimberelimab followed by adjuvant zimberelimab with or without sacituzumab govitecan in patients with resectable non-small cell lung cancer.

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Background: Phase III trials, including KEYNOTE-671, have established combined neoadjuvant chemoimmunotherapy followed by adjuvant immunotherapy (IO) as the standard of care for resectable NSCLC. However, a notable challenge in KEYNOTE-671 and similar studies was that ~17-22% of patients did not proceed to surgery following neoadjuvant chemoimmunotherapy, highlighting the need for more tolerable regimens. Recent data from studies such as NEOpredict (which demonstrated a 100% surgical completion rate with neoadjuvant nivolumab with/without relatlimab), NeoCOAST-2 (which reported a 34% pathological complete response [pCR] rate using a neoadjuvant combination of an anti-TROP2 antibody drug conjugate [ADC], IO, and single-agent platinum, thereby surpassing the ~20% pCR rates achieved with neoadjuvant chemoimmunotherapy), and EVOKE-02 (which showed promising objective response rates of 69% and 44% with the anti-TROP2 ADC sacituzumab govitecan plus pembrolizumab in first-line metastatic NSCLC patients with PD-L1 ≥50% and PD-L1 0-49%, respectively) demonstrate that chemotherapy-sparing approaches may reduce toxicity while maintaining or enhancing efficacy. These findings highlight the potential synergistic effect of ADC plus IO, suggesting this strategy may also be an effective treatment option in the perioperative setting with potentially lower toxicity compared to chemoimmunotherapy. Additionally, long-term adverse events associated with platinum-based chemotherapy, such as neuropathy, may be lower or avoided altogether. This study aims to improve the pCR rate, reduce toxicity, enhance surgical eligibility, and personalize adjuvant treatment. **Methods:** NeoTRACE is a phase II, multicenter, open-label, single-arm study evaluating the neoadjuvant combination of sacituzumab govitecan (SG) and the PD-1 inhibitor zimberelimab (ZIM) in patients with resectable stage II to IIIB (N2) NSCLC with no known EGFR or ALK alterations. Patients will receive neoadjuvant SG 10 mg/kg IV on days 1 and 8, and ZIM 360 mg IV on day 1, every 3 weeks for 4 cycles, followed by definitive surgery as per local standards. In the adjuvant phase, patients will either continue adjuvant SG plus ZIM for up to 4 cycles, followed by ZIM only for a total of up to 13 cycles, or receive adjuvant ZIM monotherapy (as per physicians' choice). The primary endpoint is the rate of pCR in tumor and lymph nodes. Secondary endpoints include major pathological response, surgical resection rate, time to surgery, DFS, OS, safety, and quality of life. The study also explores circulating tumor DNA dynamics, TROP2 expression, and spatial transcriptomics and proteomics to identify potential biomarkers. As of June 2025, the NeoTRACE study is recruiting 50 patients across 15 sites in Germany. EudraCT: 2024-517561-16. Clinical trial information: 2024-517561-16 (EudraCT). Research Sponsor: None.