TPS8121 **Poster Session**

Efficacy of low-dose nivolumab combined with chemotherapy as neoadjuvant treatment for lung cancer.

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Background: Immune checkpoint inhibitors have revolutionized cancer treatment, providing durable responses in a substantial subset of patients. However, their high costs remain a significant barrier to access, especially in low- and middle-income countries (LMICs). Evidence from pharmacodynamic studies suggests that lower doses (LD) of anti-PD-(L)1 agents can achieve comparable receptor saturation and therapeutic efficacy without compromising outcomes. Mounting data supports the concept of treating patients with LD anti-PD(L)1 agents. For instance, the use of LD nivolumab (0.3 mg/kg) has demonstrated equivalent PD-L1 receptor occupancy and similar survival outcomes to standard doses, offering a more cost-effective alternative. Notably, at 0.3 mg/kg, up to 10 patients can be treated for the cost of treating a single patient with standard doses. While most supporting evidence pertains to advanced disease settings, data on the use of LD in curative-intent applications, such as neoadjuvant therapy for resectable non-small cell lung cancer (NSCLC), remain limited. This study investigates the efficacy and safety of LD nivolumab combined with platinum-based chemotherapy as a neoadjuvant treatment for resectable NSCLC, addressing the urgent need for affordable treatment options in LMICs. **Methods:** This is an ongoing investigator-initiated, single-arm, phase II trial conducted at Hospital de Base, São José do Rio Preto, Brazil. Eligible participants are adults with histologically confirmed stage IB-IIIA NSCLC, with known PD-L1 expression, and no actionable genomic alterations in EGFR, ALK, or ROS1. All patients will receive three cycles of nivolumab (0.3 mg/kg IV every three weeks) combined with carboplatin (AUC 5-6) and either pemetrexed or paclitaxel, selected based on tumor histology and physician preference. Surgery will be scheduled 9-12 weeks after initiating therapy. The co-primary endpoints are major pathologic response rate (MPR), defined as ≤10% viable tumor cells in the resected surgical specimen, and complete pathologic response. Secondary endpoints include disease-free survival, overall survival, and treatment-related adverse events (AEs) graded per CTCAE v5.0. Exploratory analyses will evaluate outcomes based on disease stage, PD-L1 levels, and smoking history. The trial employs a Simon two-stage design with an initial cohort of 17 patients to assess futility. If at least one MPR is observed, enrollment will expand to a total of 33 patients. This design aims to detect an improvement in MPR from 12% (null hypothesis) to 24% (alternative hypothesis), with a significance level of 0.1 and 80% power. All specimens will undergo pathological review, and blood samples will be collected for exploratory biomarker analyses, including circulating tumor DNA. Study enrollment began in January 2024, and as of December 2024, 5 patients have been screened, with 3 enrolled. Clinical trial information: NCT06667154. Research Sponsor: Hospital de Base de Sao Jose do Rio Preto.