TPS4228 **Poster Session**

ALTER-PA001: A multicenter, randomized study of anlotinib and benmelstobart in combination with AG chemotherapy vs. AG as first-line treatment for metastatic pancreatic cancer.

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Background: Metastatic pancreatic cancer (mPC) remains one of the most challenging malignancies to treat, with limited effective therapeutic options. While AG chemotherapy (nab-paclitaxel and gemcitabine) is a current standard first-line regimen, new combinations are needed to improve outcomes. Preclinical data suggest potential synergistic effects of anlotinib, a multi-target tyrosine kinase inhibitor, and benmelstobart, a novel anti-PD-L1 antibody, with chemotherapy. This study aims to evaluate the efficacy and safety of this combination in mPC. **Methods:** ALTER-PA-001 is a multicenter, open-label, randomized, controlled phase 2 trial that compared anlotinib plus benmelstobart and AG with AG in patients with treatment-naïve mPC. Eligible patients are aged 18-75, ECOG 0-1, with histologically or cytologically confirmed PC. A total of 104 patients will be randomly assigned in a 2:1 ratio to receive anlotinib (8 mg orally, QD, d1–14), benmelstobart (1200 mg IV, d1), nab-paclitaxel (125 mg/m^2 IV, d1, d8), and gemcitabine (1000 mg/m^2 IV, d1, d8) every 21 days or AG regimen with nab-paclitaxel and gemcitabine at the same doses and schedule. The randomisation is done centrally and stratified by the presence of liver metastasis. Patients achieving CR, PR, or SD after 8 cycles will enter a maintenance phase with continued treatment based on their assigned arm. Tumor assessment is performed every 6 weeks for induction treatment, and every 9 weeks for maintenance phase. The primary endpoint is objective response rate (ORR), with secondary endpoints including progression-free survival (PFS), disease control rate (DCR), duration of response (DoR), overall survival (OS), and safety. Exploratory biomarker analyses will assess correlations between baseline tumor characteristics and therapeutic outcomes. This trial is actively recruiting in November 2024. Clinical trial information: NCT06621095. Research Sponsor: None.