TPS2690 **Poster Session**

Phase II basket study to evaluate the tissue-agnostic efficacy of anti-PD1 in patients with advanced rare tumors: The ANTARES trial.

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Background: Rare tumors account for 25-30% of all malignancies; however, patients (pts) with these cancers are underrepresented in clinical trials. The limited evidence on sequential oncologic treatment strategies in this population leads to a poorer prognosis compared to pts with more common malignancies. The predictive role of the tissue-agnostic biomarker PD-L1 and the combined positive score (CPS) in determining the efficacy of anti-PD1 therapy remains poorly understood in this population. **Methods:** ANTARES TRIAL (NCT06638931) is a basket phase 2 single-arm multicentric study to evaluate the efficacy of anti-PD 1 in rare tumors. Key inclusion criteria are invasive neoplasia with incidence lower than 6/100.000 people-year, expressing PD-L1 with a combined positive score (CPS) ≥10, ECOG 0-1, measurable disease by RECIST v1.1, progression or intolerance to all available treatments for metastatic disease. Patients will receive nivolumab 480 mg intravenously every 4 weeks until disease progression or for a maximum duration of 12 months. The primary endpoint was the disease control rate (DCR) assessed by RECIST v1.1. Based on Simon's two-stage design (DCR under alternative hypothesis > 25%; DCR under null hypothesis ≤5%), nine patients were accrued in the first stage. If ≥1 responses are observed, the trial will accrue an additional 16 pts. The study will be considered positive if 4 or more pts achieve DCR among 25 pts in the second stage. Considering a drop-out rate of 10%, a sample size of 28 patients will be needed to attain 90% power and alpha 0.05. Secondary endpoints include progression-free survival, overall survival, response duration, and response time. Blood samples for circulating tumor DNA, microvessels, and seric immune checkpoint biomarkers will be collected at screening, at 8, 20, 32, 44 weeks, and at the final visit. Enrollment started in Brazil on June/24 at Instituto do Câncer do Estado de São Paulo (ICESP) and Instituto D'Or de Pesquisa e Ensino (IDOR); 8 sites are planned to open later in 2025. Clinical trial information: NCT06638931. Research Sponsor: FINEP - Financiadora de Estudos e Projetos, Brazil; Reference 1676/22 protocol FADDE222-E1AE-45D9-A318-0C8477BEA1D9.