TPS2692 Poster Session

A multi-center, single-arm, phase II study of pemigatinib combined with immune checkpoint inhibitor in FGFR1/2/3 alteration advanced solid tumor.

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Background: FGFR mutations are a significant genetic factor contributing to the onset and progression of various cancers. FGFRs are aberrantly activated, including single-nucleotide variants, gene fusions, and copy number amplifications in human cancer. FGFR mutation alterations are most commonly observed in urothelial carcinoma, breast cancer, endometrial cancer, squamous cell carcinoma of the lung, etc. The preliminary efficacy of FGFR inhibitors in solid tumors has been established ORR ranged from 20% to 30% [1,2,3]. However, the efficacy of FGFR inhibitors as monotherapy in treating FGFR mutations of solid tumors has not yet met the clinical needs. Evidence from preclinical research suggested that a combination of FGFR inhibition and PD-1 suppression expanded the T-cell clones and caused immunological changes in the tumor microenvironment to enhance anti-tumor immunity and survival [4]. Based on the synergistic interplay between the FGFR signaling pathway and immune mechanisms, this study aims to evaluate the safety and efficacy of combining the FGFR inhibitor pemigatinib plus PD-1 inhibitor to treat solid tumors harboring FGFR mutations. **Methods:** 1. This study is a single-arm, multicenter, prospective Phase II clinical trial. Gene testing confirms FGFR1/2/3 variants, including but not limited to mutations, fusions/rearrangements in solid tumors. 2. Patients have not previously used specific small molecule multi-target inhibitors of the FGFR pathway, as assessed by investigators, and have been treated with immune checkpoint inhibitors. 3. Patients receive pemigatinib (13.5 mg QD, orally, 2 weeks on 1 week off, 21 days per-cycle), with immune checkpoint inhibitor therapy (strictly follow instructions). Treatment should continue until disease progression or unacceptable toxicity occurs of intolerable toxicities. 4. At least one measurable lesion per RECIST v1.1 criteria. 5. The safety of the study will be assessed using the NCI-CTCAE v5.0 criteria. The primary outcome measures: objective response rate (ORR). Secondary outcome measures: disease control rate (DCR), progression-free survival (PFS); overall survival (OS); safety and quality of life. Clinical trial information: NCT06551896. Research Sponsor: None.