TPS4626 **Poster Session**

Sasanlimab as bladder-sparing maintenance treatment after neoadjuvant chemotherapy in patients with muscle invasive bladder cancer (MIBC): The phase 2, SASAN-SPARING trial.

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Background: Radical cystectomy (RC), traditionally considered the gold standard for MIBC, carries significant morbidity, negatively impacting patients' quality of life. Recent studies have demonstrated that neoadjuvant cisplatin-based chemotherapy combined with immunotherapy can induce a complete or major pathological response in a subset of patients, allowing consideration of less invasive therapeutic alternatives. High comorbidity rates in MIBC often preclude radical cystectomy. Sasanlimab, a PD-1 inhibitor, may enhance the efficacy of neoadjuvant chemotherapy, potentially enabling bladder preservation in responding patients and improving outcomes. **Methods:** The SASAN-SPARING trial is a single-arm, non-randomized, non-blinded, phase 2 trial that evaluates the efficacy and safety of sasanlimab as a maintenance treatment in patients with localized MIBC that undergo a bladder sparing strategy with neoadjuvant cisplatin-based chemotherapy. A total of 70 patients will be accrued in 10 hospitals of Spain. Patients are $\geq$ 18 years, ECOG 0-1 and treatment-naïve for MIBC candidates to receive neoadjuvant cisplatin/gemcitabine followed by RC. All patients receive 4 cycles of neoadjuvant chemotherapy with cisplatin (70 mg/m2) on day 1 every 3 weeks and gemcitabine (1000 mg/m2) on days 1 and 8 of a 3-week cycle. After neoadjuvant chemotherapy, patients are restaged and those achieving a clinical response (absence of disease by cytology, imaging, and cT0/Ta/T1/Tis) are allowed to proceed without RC and receive maintenance with sasanlimab 300 mg subcutaneous every 4 weeks for up to 12 cycles. Tumor assessments including MRI, cystoscopy and cytology are scheduled every 12 weeks. The primary endpoint is the bladder-intact overall survival (biOS) rate at 12 months after the first dose of sasanlimab. Assuming a 12-month biOS of 81% (H0) and an increase with sasanlimab up to 93% (H1), the study requires 70 patients included of which 47 are treated with sasanlimab (one arm survival test; α = 0.05 β= 0.8). The study includes an ambitious biomarker substudy to evaluate the use of ctDNA in blood and urine samples for tumor assessment and molecular dynamics under therapeutic pressure. In addition, gut microbiome and tumor samples will be used for this end. Study of biomarkers will provide a useful tool to corroborate achievement of a clinical complete response, contributing to personalized treatments. The study is approved and started with recruitment of patients in December 2024. Clinical trial information: NCT06623162. Research Sponsor: Fundación de Investigación HM Hospitales supported by a grant (#87884561) from Pfizer.