TPS4628 Poster Session

SOGUG-NEOWIN: A phase 2, open-label, multicenter, multinational interventional trial evaluating the efficacy and safety of erdafitinib (ERDA) monotherapy and the combination of ERDA and cetrelimab (CET) as neoadjuvant treatment in cisplatin-ineligible patients with muscle-invasive bladder cancer (MIBC) harboring FGFR gene alterations.

Guillermo de Velasco, Andrea Necchi, Yohann Loriot, Syed A. Hussain; Hospital 12 de Octubre, Madrid, Spain; IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; Gustave Roussy, Département de Médecine Oncologique et Département des Essais Précoces, Université Paris-Saclay, Villejuif, France; University of Sheffield, Sheffield, United Kingdom

Background: The standard treatment for nonmetastatic MIBC is neoadjuvant cisplatin-based chemotherapy followed by radical cystectomy (RC). However, many patients are ineligible for cisplatin-based therapy. Immune checkpoint inhibitors (ICIs) have transformed the treatment of metastatic urothelial cancer (mUC), particularly for cisplatin-ineligible patients. Emerging evidence suggests that ICIs may also have potential as neoadjuvant therapy in resectable urothelial cancer, with preliminary data showing antitumor activity. Erdafitinib (ERDA), an FGFR inhibitor, has demonstrated efficacy in advanced urothelial cancer with FGFR2/3 mutations or fusions. In the phase 2 NORSE trial, ERDA combined with CET showed clinically meaningful activity in newly diagnosed FGFR-altered mUC. This study evaluates whether ERDA ± CET improves the pathological complete response (pCR) rate in FGFR-positive MIBC patients eligible for RC but ineligible for or declining cisplatin-based neoadjuvant therapy. **Methods:** SOGUG-NEOWIN is a prospective, non-comparative, open-label, multicenter trial assessing 9 or 12 weeks of neoadjuvant ERDA (cohort 1) or ERDA + CET (cohort 2) in patients with MIBC (cT2–T4a N0/1 M0) and FGFR alterations. Eligibility criteria include ECOG PS 0–1; predominant urothelial carcinoma histology; cisplatin ineligibility (GFR $<$ 60 mL/min, ≥grade 2 hearing loss, or ≥grade 2 neuropathy) or refusal; fitness for RC; no prior FGFR-targeted or anti-PD-(L)1 therapy, systemic therapy, or surgery (except TURBT or biopsies); prior BCG therapy allowed if completed ≥6 weeks before study treatment; and no current retinopathy. A total of 45 patients per cohort will be centrally allocated. Co-primary endpoints are pCR rate and pathological downstaging response ($<$ ypT2). Secondary endpoints include event-free survival, overall survival, response rate, safety, tolerability, and delay to surgery. Exploratory endpoints include biomarkers of response and resistance (baseline tissues, blood, urine), quality of life (FACT-Bl, EQ-5D-5L), and PET-MRI tumor response in a subset of patients. This trial is approved in 4 countries (6 sites in Spain, 3 in Italy, 5 in the UK, 5 in France) and is the first to systematically evaluate ERDA ± CET in FGFR-positive MIBC. The first patient was pre-screened on January 31, 2024. As of January 21, 2025, 68 patients were pre-screened, 6 were FGFR2/3-positive, and 4 were enrolled. (EU CT Number 2024-512573-27-01). Clinical trial information: 2024-512573-27-01. Research Sponsor: Johnson & Johnson.