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Neoadjuvant tislelizumab plus disitamab vedotin for UTUC: Mid-term results of the phase II WUTSUP-02 trial

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Background

Radical nephroureterectomy (RNU) is the standard treatment for localized high-risk upper tract urothelial carcinoma (UTUC), yet the high risk of recurrence and systemic progression remains a formidable challenge. While disitamab vedotin (DV) plus immunotherapy has shown remarkable efficacy in advanced urothelial carcinoma, evidence for its use in the neoadjuvant setting remains limited. The WUTSUP-02 trial (ChiCTR2300067836) is a prospective, multi-center, phase II study evaluating perioperative tislelizumab plus DV for UTUC. Herein, this mid-term analysis presents updated findings from the expanded cohort, offering further insights into this novel therapeutic strategy.

Methods

This study enrolled patients with localized high-risk or locally advanced UTUC (cT2–4N0-2M0), regardless of HER2/PD-L1 status. Neoadjuvant therapy: 4 cycles of tislelizumab (200mg) plus DV (2.0mg/kg) Q3W. RNU was performed upon completion per investigator discretion, followed by 8 cycles of adjuvant tislelizumab. Co-primary endpoints: pCR (ypT0N0M0) and ORR. Secondary endpoints: OS, MFS, and safety.

Results

By May 2026, 42 patients were enrolled (39 completed RNU). Median age: 65; 88.1% had high-grade tumors. HER2 status: 3+ (19.0%), 2+ (57.1%), and 1+ (16.7%). For the 39 evaluable patients, pCR was 28.2% (11/39) and ORR was 79.5% (31/39). In the HER2-positive (IHC 2+/3+) subgroup (n=32), pCR and ORR were 31.3% and 87.5%, vs 14.3% and 42.9% in the HER2-low (IHC 1+) subgroup (n=7). With a 24-month median follow-up (IQR 16–30), 2-year OS and MFS were 87.1% and 83.9%. Common TRAEs included liver function abnormality, alopecia, hyperglycemia, and hypoesthesia, all manageable.

Conclusions

The perioperative sequential strategy of tislelizumab and DV demonstrates promising antitumor activity and a manageable safety profile in localized high-risk or locally advanced UTUC patients. The notably higher pathological and clinical response rates observed in the HER2-positive subgroup highlight the potential of DV-immunotherapy combinations as a precision medicine approach. Ongoing patient recruitment and follow-up will enable further validation of these findings.

Clinical trial identification

ChiCTR2300067836.

Legal entity responsible for the study

West China Hospital of Sichuan University.

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Disclosure

All authors have declared no conflicts of interest.

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