TPS4624 **Poster Session**

PUNCH03: A phase II study of disitamab vedotin combined with tislelizumab and bacillus Calmette-Guerin (BCG) in Her2-positive high-risk non-muscle-invasive bladder cancer (HR NMIBC).

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Background: Disitamab vedotin (RC48) was a novel antibody drug conjugate that targets the Her2 protein. The KEYNOTE-057 study has supported the benefits of PD-1 inhibitor in HR NMIBC patients (pts). Our study was established to evaluate the efficacy and safety of RC48 combined with tislelizumab and BCG as a bladder-preserving treatment for Her2-positive HR NMIBC pts. **Methods:** This open-label phase II study enrolled BCG-naïve HR NMIBC pts with multiple papillary tumors (high-grade Ta or T1 tumors), and all pts were Her2-positive (IHC 2+ or 3+). Firstly, the papillary tumors should be removed all visible lesions by transurethral resection of bladder tumor (TURBT). Secondly, pts were administered RC48 (2.0 mg/kg, ivgtt), every 2 weeks for 1 cycle, and were administered tislelizumab (200 mg, ivgtt), every 3 weeks for 1 cycle. Then, pts received second TURBT, and pts were administered 3 cycles of RC48 (2.0 mg/kg, Q2W, ivgtt) and tislelizumab (200mg, Q3W, ivgtt). Finally, pts received 18 instillations of BCG plus at least 1 year of tislelizumab (200 mg, Q3W, ivgtt). Specifically, pts were started on an induction course of BCG with 6 instillations every week, followed by maintenance with 3 instillations every 2 weeks and 9 instillations every 4 weeks. The primary end point was recurrence-free survival (RFS) rate at 12 months. Secondary end points were bladder-preservation rate, OS and safety. Our study estimated a RFS rate at 12 months was no less than 85% and the study would enroll 38 pts. Clinical trial information: ChiCTR2400093839. Research Sponsor: None.