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TQB2102, a novel HER2 bispecific antibody-drug conjugate, combined with bemotrizumab with or without capecitabine as first-line therapy for HER2-positive advanced gastric/gastroesophageal junction cancer: A phase II study

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Background

TQB2102 is a novel bispecific HER2 ADC targeting domains 2/4, conjugated to a deuterated Topo I inhibitor (DAR=6). This is the first phase II study of a bispecific HER2 ADC combination as first-line therapy for HER2-positive advanced GC/GEJC.

Methods

This multicenter phase II trial enrolled patients with unresectable locally advanced or metastatic HER2-positive GC/GEJC, ECOG PS 0–1, no prior systemic therapy. Patients were assigned to three cohorts: A (TQB2102 7.5 mg/kg + bemotrizumab), B (7.5 mg/kg + bemotrizumab + capecitabine 1000 mg/m²), C (6 mg/kg + bemotrizumab + capecitabine). Primary endpoint: ORR; secondary endpoints: DCR, TTR, DOR, PFS, OS, safety.

Results

As of February 28, 2026, 86 eligible patients were enrolled (A: 25; B: 37; C: 24) with balanced baseline characteristics. As shown in the table, triple combinations (B/C) showed higher ORR/DCR and shorter TTR versus dual therapy (A). Median PFS and OS were not reached, and triple-combination arms achieved superior 6-month PFS and 9-month OS rates. Among triple combinations, TQB2102 at 6 mg/kg demonstrated more favorable efficacy than at 7.5 mg/kg. Subgroup analyses showed consistent antitumor activity regardless of PD-L1 expression status. Treatment-related adverse events (TRAEs) occurred in all patients; grade ≥3 TRAEs were reported in 56% of the dual-agent cohort and 60.66% of triple-combination patients (41.67% in Cohort C, 72.97% in Cohort B). All events were manageable and reversible with no new safety signals identified.

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Cohort	ORR, %	DCR, %	TTR(m)	6-m PFS (%)	9-m OS (%)	PD-L1 CPS <1, ORR (%)	PD-L1 CPS <1, 6-month PFS (%)	PD-L1 CPS ≥1, ORR (%)	PD-L1 CPS ≥1, 6-month PFS (%)
A	69.6	95.7	2.6	71.4	81.5	50	40	73.7	77
B	80	100	1.4	70	83.4	72.7	53.8	84.2	81.4
C	94.7	100	1.5	92.3	100	100	100	92.9	87.5
B+C	85.7	100	1.4	77.5	88.1	81.3	66.2	87.9	83.8

Conclusions

TQB2102 plus bemotrizumab and capecitabine demonstrates promising antitumor activity and a manageable safety profile as first-line treatment for HER2-positive advanced GC/GEJC. The 6.0 mg/kg dose of TQB2102 provides an optimal benefit–risk balance and has been selected as the recommended phase III dose. A phase III trial is planned.

Clinical trial identification

NCT06767800.

Legal entity responsible for the study

Chia Tai Tianqing Pharmaceutical Group Nanjing Shunxin Pharmaceutical Co., Ltd.

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Disclosure

All authors have declared no conflicts of interest.

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