

LBA27

APEX-Breast01: TQB2102 versus chemotherapy in HER2-low recurrent or metastatic breast cancer (r/m BC) - Results from a randomized phase 3 study

S. Wang¹, Q. Zhang², Y. Shi³, N. Li⁴, Z. Shao⁵, T. Sun⁶, H. Li⁷, J. Cui⁸, C. Hao⁹, M. Yan¹⁰, Y. Teng¹¹, X. Tang¹², J. Ding¹³, Y. Peng¹⁴, Y. Pan¹⁵, F. Wang¹⁶, F. Feng¹⁷, X. Yang¹⁸, Y. Li¹⁹, X. Kang²⁰

¹ Department of Medical Oncology, Sun Yat-sen University Cancer Center, Guangzhou, China, ² Department of Breast Medicine 1, Harbin Medical University Cancer Hospital, Harbin, China, ³ Department of Breast Medical Oncology, Tianjin Medical University Cancer Institute & Hospital, Tianjin, China, ⁴ Department of Thyroid and Breast Surgery, Xijing Hospital of PLA Air Force Military Medical University, Xi'an, China, ⁵ Department of Breast Surgery, Fudan University Shanghai Cancer Center, Shanghai, China, ⁶ Department of Medical Oncology, Liaoning Cancer Hospital and Institute, Shenyang, China, ⁷ Department of Breast Medical Oncology, Cancer Hospital of Shandong First Medical University, Jinan, China, ⁸ Department of Medical Oncology, The First Hospital of Jilin University, Changchun, China, ⁹ Department of Breast Medical Oncology, Tianjin Cancer Hospital Airport Hospital, Tianjin, China, ¹⁰ Department of Breast Medicine, Henan Cancer Hospital, Zhengzhou, China, ¹¹ Department of Medical Oncology, The First Affiliated Hospital of China Medical University, Shenyang, China, ¹² Breast Tumor Center, Chongqing University Cancer Hospital, Chongqing, China, ¹³ Department of Breast Surgery, Ningbo Medical Treatment Center Lihuili Hospital, Ningbo, China, ¹⁴ Department of VIP Medical Services, Chinese Academy of Medical Science - National Cancer Center, Cancer Hospital, Beijing, China, ¹⁵ Department of Medical Oncology, Anhui Provincial Hospital, Hefei, China, ¹⁶ Department of Breast Surgery, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China, ¹⁷ Department of Clinical Medicine, Chia Tai Tianqing Pharmaceutical Group Co., Ltd., Nanjing, China, ¹⁸ Department of Biostatistics, Chia Tai Tianqing Pharmaceutical Group Co., Ltd., Nanjing, China, ¹⁹ Department of Marketing, Chia Tai Tianqing Pharmaceutical Group Co., Ltd., Shanghai, China²⁰ Clinical Research & Development Center, Chia Tai Tianqing Pharmaceutical Group Co., Ltd., Shanghai, China

Background

TQB2102, a novel biparatopic HER2-targeting antibody-drug conjugate, showed potential antitumor activity in heavily-treated patients (pts) with HER2-low (IHC 1+ or 2+/ISH-) mBC in phase 1 and phase 1b trials. Here, we report the interim analysis results from the phase 3 APEX-Breast01 study.

Methods

Pts with HER2-low r/m BC who had no prior advanced chemotherapy were recruited, including HR+ pts who had disease progression after ≥1 line of endocrine therapy for metastatic disease, and HR- pts with CPS<1 or unknown status. Pts were randomized 1:1 to TQB2102 7.5mg/kg Q3W or treatment of physician's choice (TPC; Capecitabine/Paclitaxel/nab-Paclitaxel). The primary endpoint was PFS per blinded independent review committee (BIRC) in HR+/HER2-low pts. Key secondary endpoint was PFS per BIRC in all HER2-low pts.

Results

As of May 31, 2026, 543 pts (HR+: n=461, prior CDK4/6i: 91.3%) were randomized (TQB2102, n=269; TPC, n=274; IHC 1+: 58.3% vs 57.9%; prior taxane: 62.3% vs 61.8%). The PFS were significantly improved in the TQB2102 group than in the TPC group both in HR+/HER2-low pts (median, 16.4 mo vs 5.5 mo; HR, 0.29 [95% CI 0.22-0.39]; *p*<0.0001) and in all HER2-low pts (median, 16.4 mo vs 5.5 mo; HR, 0.29 [95% CI 0.22-0.38]; *p*<0.0001). Despite immature OS data, TQB2102 showed a clear OS benefit trend in both HR+ pts and all HER2-low pts. Subgroup analysis showed consistent benefit trend of TQB2102 in HR-/HER2-low pts (Table). The most common grade ≥3 TRAEs were neutrophil count decreased (30.1% vs 23.3%) and WBC decreased (21.6% vs 14.0%). TRAEs led to discontinuation in 1.5% of pts in each group. TQB2102-related interstitial lung disease occurred in 6 pts (2.2%; grade 3, 1.1%).Table: LBA27

	TQB2102 HR+ (n=228)	TPC HR+ (n=233)	TQB2102 HER2-low (n=269)	TPC HER2-low (n=274)	TQB2102 HR- (n=41)	TPC HR- (n=41)
mPFS ^a , mo (95% CI)	16.4 (11.9, NE)	5.5 (4.3, 6.9)	16.4 (11.9, NE)	5.5 (4.3, 6.9)	8.5 (8.2, 14.0)	5.4 (2.9, 6.9)
PFS HR (95% CI), P value ^b	0.29 (0.22, 0.39) <i>p</i> <0.0001	0.29 (0.22, 0.38) <i>p</i> <0.0001	0.27 (0.13, 0.56)			
OS HR (95% CI)	0.47 (0.26, 0.87)	0.44 (0.25, 0.79)	0.21 (0.02, 1.85)			
ORR ^a , % (95% CI)	66.7(60.1, 72.8)	31.3 (25.4, 37.7)	68.8 (62.9, 74.3)	31.0 (25.6, 36.9)	80.5 (65.1, 91.2)	29.3 (16.1, 45.5)

NE, non-estimable. ^a by BIRC. ^b 2-sided log-rank test.

Conclusions

TQB2102 demonstrated a statistically significant and clinically meaningful improvement in PFS and a clear trend in OS benefit versus TPC in pts with HER2-low r/m BC, with a manageable safety profile, positioning it as a promising therapeutic option for this population.

Clinical trial identification

NCT06561607.

Legal entity responsible for the study

The authors.

Funding

Chia Tai Tianqing Pharmaceutical Group Co., Ltd.

Disclosure

F. Feng: Other, Personal, Full or part-time Employment, Full-time employee: Chia Tai Tianqing Pharmaceutical Group Co., Ltd. X. Yang: Other, Personal, Full or part-time Employment, Full-time Employee: Chia Tai Tianqing Pharmaceutical Co., Ltd. Y. Li: Other, Personal, Full or part-time Employment, Full-time employee: Chia Tai Tianqing Pharmaceutical Co., Ltd. X. Kang: Other, Personal, Full or part-time Employment, Full-time employee: Chia Tai Tianqing Pharmaceutical Co., Ltd. All other authors have declared no conflicts of interest.

© European Society for Medical Oncology