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Anbenitamab plus albumin-bound docetaxel in patients (pts) with HER2-positive advanced breast cancer (BC): A randomized phase III study

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Background

THP regimen is an established first-line treatment for HER2+ advanced BC. However, metastatic disease remains incurable, and nearly half of pts experienced disease progression within two years. Anbenitamab is a novel HER2 targeted bispecific antibody. Here we report the interim efficacy and safety results of anbenitamab plus HB1801 vs THP in this setting.

Methods

In this multicenter, randomized, open-label, phase 3 trial, eligible pts had histologically confirmed HER2+ advanced BC, and had received no prior chemotherapy or HER2-directed therapy for advanced disease. Pts were randomized 1:1 to receive anbenitamab plus HB1801 or THP, stratified by prior adjuvant/neo-adjuvant therapy, hormone receptor status, and visceral metastases. The primary endpoint was progression-free survival (PFS) as assessed by blinded independent review committee (BIRC). Secondary endpoints included investigator-assessed PFS, objective response rate (ORR), duration of response (DoR), overall survival (OS), and safety.

Results

A total of 885 pts were randomized (445 in the anbenitamab group and 440 in THP group). At this prespecified interim analysis cutoff (April 30, 2026; 401 PFS events), the median PFS by BIRC was not reached (95% CI 24.9, NE) in the anbenitamab group vs 14.3 months (95% CI 12.4, 16.4) in the THP group (HR, 0.46; 95% CI 0.37, 0.56; p<0.0001). A consistent improvement in investigator-assessed PFS was also observed (HR, 0.52; 95% CI 0.43, 0.64). The confirmed ORR by BIRC was 87.6% and 73.4%, respectively, with a median DoR of not reached (95% CI 27.0, NE) vs 16.6 months (95% CI 12.5, 20.8). Although OS data were immature, the anbenitamab group showed an OS benefit trend. Grade ≥ 3 treatment-related adverse events occurred in 164 (36.9%) pts in the anbenitamab group and 111 (25.3%) in the THP group, with neutropenia (13.1% vs. 8.4%) being the most common. One pt in the anbenitamab group and two pts in the THP group experienced treatment-related deaths. No new safety signals were observed.

Conclusions

Anbenitamab plus HB1801 demonstrated a significant and clinically meaningful improvement in PFS compared with THP, and may establish a new standard of care for pts with HER2+ advanced BC, with a favorable safety profile.

Clinical trial identification

NCT05838066.

Legal entity responsible for the study

Shanghai JMT-Bio Inc.

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Disclosure

W. Huang: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. S. Xiang: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. K. Zou: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical^ Group Limited. Y. Wang: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. All other authors have declared no conflicts of interest.

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