



DualityBio Announces China NMPA Acceptance of Biologics License Application Seeking Approval for Trastuzumab Pamirtecan for the Treatment of Unresectable or Metastatic HER2-Positive Adult Breast Cancer

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

SHANGHAI, April 9, 2026 /PRNewswire/ - DualityBio (DualityBio or the Company, Stock Code: 9606.HK) today announced that the Biologics License Application (BLA) for the investigational antibody-drug conjugate (ADC) trastuzumab pamirtecan (T-Pam, also known as DB-1303 or BNT323), has been accepted for review by the China National Medical Products Administration (NMPA). With the BLA filing, DualityBio is seeking approval for trastuzumab pamirtecan as second-line treatment for patients with unresectable or metastatic HER2-positive breast cancer. The application is based on positive interim results from the pivotal Phase III clinical trial (Study DB-1303-O-3001).

The DB-1303-O-3001 trial is a randomized, controlled, open-label, multicenter Phase III clinical trial conducted in China. It aims to evaluate the efficacy and safety of trastuzumab pamirtecan compared to trastuzumab emtansine (T-DM1) in patients with HER2-positive unresectable or metastatic breast cancer who have previously received trastuzumab and taxane chemotherapy. As assessed by the Independent Data Monitoring Committee (IDMC), the trial has met its primary endpoint of statistically significant improvement of progression-free survival (PFS, assessed by Blinded Independent Central Review, BICR) for trastuzumab pamirtecan compared to T-DM1 at a pre-specified interim analysis.

Dr. Hua Mu, Global Chief Medical Officer of DualityBio, stated: "China has over 350,000 new breast cancer cases annually [1], representing a high incidence rate and ranking as the second most common cancer among Chinese women. We are delighted to see that DB-1303/T-Pam has achieved a milestone in its commercialization progress, demonstrating its potential to provide an effective new treatment option for breast cancer patients. In the China market, we have entered into a collaboration with 3SBio to jointly advance the commercialization of multiple indications of DB-1303/T-Pam in Chinese mainland, Hong Kong and Macao. Globally, we will continue to deepen our global strategic partnership with BioNTech to further drive the global development of this product. DB-1303/T-Pam is a globally co-developed new drug with strong strategic partners in both China and global markets. We will

work closely together to accelerate the product's marketing approval process, maximize its global clinical value, present more treatment options to patients worldwide.

About trastuzumab pamirtecan (BNT323/DB-1303)

Trastuzumab pamirtecan (T-Pam, also known as BNT323 or DB-1303) is a third-generation topoisomerase-1 inhibitor-based ADC targeting HER2 which is being developed by BioNTech and DualityBio. Trastuzumab pamirtecan was built from DualityBio's proprietary Duality Immune Toxin Antibody Conjugates (DITAC) platform. HER2 is a surface-expressed protein on solid tumors and has been linked to the aggressive growth and spread of cancer cells, making it a potential target for innovative cancer therapeutics. The candidate has exhibited antitumor activity in both HER2-positive and HER2-low tumor models as well as in several solid tumor indications, including patients with breast and endometrial cancers, as well as other advanced solid tumors. Preclinical data and preliminary clinical data for trastuzumab pamirtecan indicate its potential to target HER2 receptors on solid tumors irrespective of expression level with a manageable safety profile and a potentially expanded therapeutic window. Trastuzumab pamirtecan is currently being evaluated in multiple solid tumor types and innovative treatment combinations, including two global pivotal clinical trials in first-line HER2-low, hormone receptor positive (HR+) metastatic breast cancer (DYNASTY-Breast02; NCT06018337) and second-line endometrial cancer (BNT323-01; NCT06340568), a novel combination Phase 1/2 clinical trial (BNT323-03; NCT06827236) evaluating trastuzumab pamirtecan in combination with pumitamicig in HR-positive or -negative, HER2-low, -ultra-low, or -null advanced/metastatic breast cancer and a Phase III, randomized, multi-site, open-label trial of BNT323/DB-1303 Versus Investigator's Choice of Chemotherapy in Previously Treated Patients With HER2- Expressing Recurrent Endometrial Cancer (NCT06340568) .

The BNT323/DB-1303 program received the Fast Track designation and Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the treatment of endometrial cancer in 2023.

About DualityBio

Duality Biotherapeutics (HKEX:09606) is a clinical-stage biotech company dedicated to the discovery and development of next-generation ADCs to treat cancer and autoimmune diseases. DualityBio has successfully built several cutting-edge ADC technology platforms with global intellectual property rights. Leveraging a robust pipeline, DualityBio is conducting multiple global clinical trials across 17 countries and has enrolled over 3,200 patients for multiple clinical-stage ADC candidates.

Additionally, DualityBio has established strategic collaborations with global MNCs and leading biotech innovators. As a global ADC powerhouse, DualityBio is developing novel ADCs, including bispecific ADC candidates, novel-payload ADC candidates, and autoimmune ADC candidates.

For more information, please visit www.dualitybiologics.com

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Data di creazione

Aprile 9, 2026

Autore

redazione

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