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Sichuan Baili Tianheng Pharmaceutical Co., Ltd.

Voluntary Disclosure Announcement Regarding the Interim Analysis of the Phase III Clinical Trial of Izalontamab Brengitecan (BL-B01D1/iza-bren) for Locally Advanced, Recurrent or Metastatic HR+HER2- Breast Cancer Meeting Its Primary Endpoint

The Board of Directors and all directors of the Company warrant that this announcement contains no false records, misleading statements, or material omissions, and assume individual and joint legal liability for the truthfulness, accuracy, and completeness of its content.

Izalontamab brengitecan (BL-B01D1/iza-bren), independently developed by Sichuan Baili Tianheng Pharmaceutical Co., Ltd. (the “Company”), is the world's first-in-class, new-concept, and the world's first and only approved and marketed EGFR×HER3 bispecific antibody-drug conjugate (ADC). In its Phase III clinical trial for HR+HER2- breast cancer (study protocol number: BL-B01D1-306), the independent Data Monitoring Committee (iDMC) determined that the pre-specified interim analysis met the primary endpoint of progression-free survival (PFS). The indication under study is: unresectable locally advanced, recurrent, or metastatic HR+HER2- breast cancer in patients who have failed at least one prior line of chemotherapy. This marks the fifth Phase III clinical study in which this bispecific ADC has met its primary endpoint, and it is also the world's first Phase III clinical study of a bispecific ADC drug to meet its primary endpoint in the treatment of HR+HER2- breast cancer.

I. Basic Information About the Drug

Izalontamab brengitecan (BL-B01D1/iza-bren) is the world's first-in-class, new-concept, and the world's first and only approved and marketed bispecific ADC. Two indications for izalontamab brengitecan—recurrent or metastatic nasopharyngeal carcinoma and recurrent or metastatic esophageal squamous cell carcinoma—have already received marketing approval from the National Medical Products Administration (NMPA). In addition, a New Drug Application (NDA) for the treatment of locally advanced or metastatic triple-negative breast cancer has also been accepted by the Center for Drug Evaluation (CDE).

As of the date of this announcement, izalontamab brengitecan has been the subject of more than 40 clinical trials across multiple tumor types in China and the United States, including 20 Phase III studies (including Phase II/III studies). Seven indications for izalontamab brengitecan have been included in the CDE's Breakthrough Therapy Designation list, two indications have been included in the CDE's Priority Review list, and one indication has been included in the U.S. Food and Drug Administration's (FDA) Breakthrough Therapy Designation list.

II. Risk Warning

In accordance with the laws and regulations governing drug registration in China, drugs must complete the relevant clinical trials and be reviewed and approved by the National Medical Products Administration before they may be marketed and sold.

Given that pharmaceutical products are characterized by high technology, high risk, and high added value, the process from clinical trial application to production involves a long cycle and many stages, and is susceptible to various uncertain factors. The Company will actively advance the above research and development projects in accordance with relevant regulations, and will strictly fulfill its information disclosure obligations regarding the subsequent progress of the project in a timely manner in accordance with relevant regulations. Investors are advised to make prudent decisions and remain mindful of investment risks.

This announcement is hereby made.

Board of Directors
Sichuan Baili Tianheng Pharmaceutical Co., Ltd.

August 26, 2026