Stock Code: 688506 Stock Abbreviation: Baili Tianheng Announcement No.: 2026-078

Sichuan Baili Tianheng Pharmaceutical Co., Ltd.

Voluntary Disclosure Announcement Regarding the Receipt of the Drug Clinical Trial Approval Notice for Izalontamab Brengitecan (BL-B01D1/iza-bren) in Combination with Radiotherapy for the Treatment of Locally Advanced Unresectable Head and Neck Squamous Cell Carcinoma and Other Solid Tumors

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.

Sichuan Baili Tianheng Pharmaceutical Co., Ltd. (the “Company”) has recently received the Drug Clinical Trial Approval Notice formally issued by the National Medical Products Administration (NMPA), approving the combination-therapy clinical trial of izalontamab brengitecan (BL-B01D1/iza-bren), the world's first-in-class, new-concept, and the world's first and only approved and marketed EGFR×HER3 bispecific ADC independently developed by the Company. The relevant information is announced as follows:

I. Basic Information About the Drug Clinical Trial Approval Notice

Product name: BL-B01D1 for Injection

Acceptance number: CXSL2600781

Notice number: 2026LP03023

Application matter: Registration clinical trial of a domestically produced drug

Applicants: Chengdu Baili Duote Biopharmaceutical Co., Ltd.; Sichuan Baili Pharmaceutical Co., Ltd.

Conclusion: Pursuant to the Drug Administration Law of the People's Republic of China and related regulations, upon review, the clinical trial of BL-B01D1 for Injection meets the relevant requirements for drug registration. Approval is granted for this product to conduct a trial in combination with radiotherapy in locally advanced unresectable head and neck squamous cell carcinoma and other solid tumors.

II. Other 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.

To date, izalontamab brengitecan has been the subject of more than 45 clinical trials across multiple tumor types in China and the United States, including 20 Phase III studies (including Phase II/III studies). Nine indications of izalontamab brengitecan have been included by the Center for Drug Evaluation (CDE) of the NMPA in the list of Breakthrough Therapy Designations, two indications have been included by the CDE in the list of Priority Review designations, and one indication has been included by the U.S. Food and Drug Administration (FDA) in the list of Breakthrough Therapy Designations.

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); a New Drug Application (NDA) for the treatment of locally advanced or metastatic triple-negative breast cancer has also been accepted by the CDE; and two indications, locally advanced or metastatic EGFR-mutant non-small cell lung cancer and HR+HER2- breast cancer, have met their primary endpoints in interim analyses.

III. 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 early-stage research and 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 project 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.

October 12, 2026