

Sichuan Baili Tianheng Pharmaceutical Co., Ltd.

Voluntary Disclosure Announcement Regarding the Inclusion of BL-M05D1 for Injection (Claudin18.2 ADC) for Patients with CLDN18.2-Positive Advanced Gastric Cancer or Gastroesophageal Junction Adenocarcinoma Who Have Previously Received First-Line Standard Therapy in the List of Breakthrough Therapy Designations

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.

The regimen of BL-M05D1 for Injection (Claudin18.2 ADC), an innovative biological drug independently developed by Sichuan Baili Tianheng Pharmaceutical Co., Ltd. (the “Company”), for patients with CLDN18.2-positive advanced gastric cancer or gastroesophageal junction adenocarcinoma (GC/GEJC) who have previously received first-line standard therapy has been included by the Center for Drug Evaluation (the “CDE”) of the National Medical Products Administration in the list of Breakthrough Therapy Designations. The main details are announced as follows:

I. Basic Information About the Drug

Drug name	BL-M05D1 for Injection
Acceptance number	CXSL2300904
Drug type	Therapeutic biological product
Registration category	1
Application date	August 13, 2026
Proposed indication (or functions and indications)	Patients with CLDN18.2-positive advanced gastric cancer or gastroesophageal junction adenocarcinoma (GC/GEJC) who have previously received first-line standard therapy
Reasons and basis	Upon review, this application complies with the Provisions for Drug Registration and the Announcement of the National Medical Products Administration on Issuing Three Documents Including the “Working Procedures for the Review of Breakthrough Therapy Drugs (Trial)” (Announcement No. 82 of 2020). Inclusion in the Breakthrough Therapy Drug procedure is approved.

II. Other Information About the Drug

BL-M05D1 for Injection is an innovative ADC targeting Claudin18.2, independently developed by the Company. It originates from the same technology platform as Izalontamab Brengitecan (BL-B01D1/iza-bren) and shares the same “linker + toxin” platform. This is the first time BL-M05D1 for Injection has been included by the CDE in the list of Breakthrough Therapy Designations.

To date, BL-M05D1 for Injection is being studied in 3 clinical trials in China and abroad, including 1 Phase III, 1 Phase Ib, and 1 Phase Ia clinical trial, with locally advanced solid tumors as the indication. Among them, the randomized controlled Phase III clinical trial comparing BL-M05D1 for Injection with an investigator-selected treatment regimen in patients with CLDN18.2-positive advanced gastric cancer or gastroesophageal junction adenocarcinoma who have previously received first-line therapy completed enrollment of its first subject in June 2026.

III. Risk Warning

Pursuant to the Announcement of the National Medical Products Administration on Issuing Three Documents Including the Working Procedures for the Review of Breakthrough Therapy Drugs (Trial) (Announcement No. 82 of 2020), the CDE will give priority in resource allocation for communication and exchange regarding drugs included in the Breakthrough Therapy Drug procedure, and will strengthen guidance and promote drug development.

Drug research and development is susceptible to many factors, including technology, approval, and policy. There are numerous uncertainty risks in review policies and the future competitive landscape of the drug market. Investors are advised to make prudent decisions and remain mindful of investment risks. 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 projects in a timely manner in accordance with relevant regulations.

This announcement is hereby made.

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

September 28, 2026