Stock Code: 688506 Stock Abbreviation: Baili Tianheng Announcement No.: 2025-086

Sichuan Baili Tianheng Pharmaceutical Co., Ltd.

Voluntary disclosure regarding **iza-bren (EGFR×HER3** bispecific antibody ADC) for the treatment of

Announcement of Acceptance of Drug Marketing Applications for Locally Advanced or Metastatic Nasopharyngeal Carcinoma

The Board of Directors and all directors of the Company guarantee that the contents of this announcement do not contain any false records or misleading statements.

Or, if there are any major omissions, the party shall bear legal responsibility for the authenticity, accuracy and completeness of its content in accordance with the law.

Recently, Sichuan Baili Tianheng Pharmaceutical Co., Ltd. (hereinafter referred to as "the Company") received a notice from the National Medical Products Administration.

The "Acceptance Notice" approved and issued by the Supervision and Administration Bureau indicates that the company's independently developed product is a world-first (first-in-class) innovation.

A novel concept and the only EGFR×HER3 bispecific antibody ADC to enter Phase III clinical trials.

The drug marketing application (NDA) for (iza-bren) has been formally accepted.

This acceptance is based on the interim analysis results of the BL-B01D1-303 study. Previously, the company had already cooperated with the National Medical Products Administration.

The Center for Drug Evaluation (CDE) of the State Drug Administration successfully completed the Pre-NDA (Pre-NDA) meeting.

According to reports, iza-bren, used to treat locally advanced or metastatic nasopharyngeal carcinoma, has been included in the priority review list by the CDE (Center for Drug Evaluation).

List. The relevant information is hereby announced as follows:

I. Basic Information about the Drugs

Drug Name: BL-B01D1 for Injection/iza-bren

Dosage form: Injection

Case Number: CXSS2500124

Applicant: Chengdu Bailidote Biopharmaceutical Co., Ltd.

Proposed indication (or therapeutic function): This product is indicated for patients who have previously received PD-1/PD-L1 monoclonal antibody therapy and have reached [a certain level of clinical remission/treatment].

Patients with recurrent or metastatic nasopharyngeal carcinoma who have failed at least two lines of chemotherapy (at least one line of platinum-based chemotherapy).

II. Other information regarding medicines

Iza-bren is a world-first, new concept, and the only one to enter the III level.

This EGFR×HER3 bispecific antibody ADC, currently in Phase II clinical trials, is also the world's first drug to have its marketing application accepted.

EGFR×HER3 bispecific antibody ADC. iza-bren is currently conducting over 40 trials in China and the United States targeting various tumor types.

Clinical trials are underway. To date, iza-bren has been included in the CDE's Breakthrough Therapy designation for seven indications.

One indication was included in the priority review list by the CDE, and another indication was approved by the US Food and Drug Administration.

The regulatory authority included it in the list of breakthrough treatment products.

III. Risk Warning

According to the relevant laws and regulations on drug registration in my country, after a drug's marketing application is accepted, it still needs to be...

It can only be marketed and sold after passing the relevant review procedures of the National Medical Products Administration and obtaining approval.

Because pharmaceutical products are characterized by high technology, high risk, and high added value, the approval process for drugs from clinical trials...

The production cycle is long and involves many steps, making it susceptible to uncertainties. The company will proceed in accordance with relevant regulations.

Actively promote the aforementioned R&D projects and strictly comply with relevant regulations to promptly report on the subsequent progress of the projects.

Due to disclosure obligations, investors are advised to make prudent decisions and be aware of investment risks.

This is to announce.

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

November 24, 2025