Stock Code: 688506 Stock Abbreviation: Baili Tianheng Announcement No.: 2026-007

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 Application for Recurrent or Metastatic Esophageal Squamous Cell 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 responsible shall bear legal responsibility for the authenticity, accuracy and completeness of its content.

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" issued by the Center for Drug Evaluation (CDE) of the State Drug Administration, and the company's independently developed...

The world's first-in-class, new-concept, and only technology to enter Phase III clinical trials.

The drug application (NDA) for EGFR×HER3 bispecific antibody ADC (iza-bren) has been formally accepted.

Previously, iza-bren was used in a phase III clinical trial for esophageal squamous cell carcinoma (study protocol number: BL-B01D1-305).

In the interim analysis, the data was determined by the Independent Data Monitoring Committee (iDMC) to have reached progression-free survival.

The primary endpoints were progression-free survival (PFS) and overall survival (OS). This NDA acceptance is based on this Phase III clinical trial.

Interim analysis results of the trial showed that iza-bren, used to treat recurrent or metastatic esophageal squamous cell carcinoma, has also been included by the CDE (Center for Drug Evaluation).

List of varieties eligible for priority review. 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: CXSS2600012

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 combined with platinum-containing drugs.

For patients with recurrent or metastatic esophageal squamous cell carcinoma who have failed treatment.

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.

Two indications were included in the priority review list by the CDE, and one indication was approved by the US Food and Drug Administration.

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

In addition to this NDA acceptance, there are also NDA applications for iza-bren for the treatment of locally advanced or metastatic nasopharyngeal carcinoma.

The application has been accepted.

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.

January 21, 2026