

Sichuan Baili Tianheng Pharmaceutical Co., Ltd.

Voluntary disclosure regarding the use of iza-bren (EGFR×HER3 bispecific antibody ADC) for local application

Interim analysis of a phase III clinical trial for advanced or metastatic triple-negative breast cancer

Announcement of reaching the main endpoint

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.

The Independent Data Monitoring Committee (IDMC) for this Phase III clinical trial, in its pre-specified interim analysis, established...

The suggestion is: "Based on the existing analysis results, we will communicate with regulators to submit the application in advance, while continuing to follow up with the participants."

Topline data showed that iza-bren significantly prolonged progression-free survival (PFS) and overall survival (OS).

Achieved both primary endpoints. The indication is: treatment of unresectable localized lesions that have failed prior taxane therapy.

Advanced or metastatic triple-negative breast cancer. This is the third Phase III clinical trial of this bispecific antibody ADC to meet its primary endpoint.

This study is also the world's first to show that a bispecific antibody ADC drug achieved double-positive PFS/OS results in the treatment of triple-negative breast cancer.

Phase III clinical trial (study protocol number: BL-B01D1-307).

I. Basic Information about the Drugs

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

Iza-bren, an EGFR×HER3 bispecific antibody ADC in Phase I clinical trials, is currently undergoing more than 40 needle trials in China and the United States.

Clinical trials on multiple tumor types.

To date, iza-bren has been included in 7 indications by the Center for Drug Evaluation of the National Medical Products Administration.

Breakthrough Therapy Product List: One indication has been included in the U.S. Food and Drug Administration's Breakthrough Therapy Product list.

The list includes two indications for iza-bren: for the treatment of locally advanced or metastatic nasopharyngeal carcinoma and for the treatment of...

The New Drug Application (NDA) for recurrent or metastatic esophageal squamous cell carcinoma has been approved by the National Medical Products Administration.

The product was accepted by the Center for Drug Evaluation (CDE) and included in the priority review process.

II. Risk Warning

According to the relevant laws and regulations on drug registration in my country, drugs need to complete relevant clinical trials and pass [the relevant approval process].

It can only be marketed and sold after being reviewed and approved by the National Medical Products Administration.

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.

February 24, 2026