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Jiangsu Hengrui Medicine Co., Ltd.

Announcement Regarding the Inclusion of Drugs in the Breakthrough Therapy List

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.

Recently, Suzhou Shengdiya Biotech, a subsidiary of Jiangsu Hengrui Medicine Co., Ltd. (hereinafter referred to as "the Company")

SHR-1826 for injection from Wuyi Pharmaceutical Co., Ltd. has been approved by the Center for Drug Evaluation of the National Medical Products Administration (hereinafter referred to as the Center).

The Center for Drug Evaluation (CDE) has included [the drug] in its list of breakthrough therapies. The relevant information is hereby announced as follows:

I. Basic Information about the Drug

Drug Name: SHR-1826 for Injection

Case Number: CXSL2300466

Drug type: Therapeutic biological products

Registration Category: Class 1

Application date: December 1, 2025

Proposed indication (or therapeutic use): Monotherapy for patients who have failed at least one line of systemic therapy.

c-Met overexpression (2-3+, ≥50%) driver gene negative locally advanced or metastatic non-squamous non-small cell lung cancer

Lung cancer.

Reasons and basis: After review, this application complies with the "Regulations for Drug Registration Management" and the "Regulations of the National Medical Products Administration".

Announcement on the Issuance of Three Documents Including the "Trial Procedures for the Review of Breakthrough Therapy Drugs" (2020)

In accordance with the requirements of No. 82, we agree to include it in the Breakthrough Therapy program.

II. Other relevant information about the drug

Lung cancer is currently the leading cause of cancer death worldwide, and both its incidence and mortality rates are on the rise year by year.

In my country, lung cancer ranks first in both incidence and mortality among malignant tumors. In 2022, the number of new lung cancer cases in my country...

For example, there were 1,060,600 cases, accounting for 22.0% of all malignant tumors, and 733,300 deaths, accounting for [a significant percentage] of all malignant tumor deaths.

28.5%. Clinically, about half of the patients are already in the late stage when they present with symptoms, and their 5-year survival rate is only about 20%.

This is one of the major challenges facing China's public health sector [1].

SHR-1826 for injection is an antibody-drug conjugate targeting c-Met, which works by binding to the surface of tumor cells.

It specifically binds to the target antigen, is internalized into tumor cells, and then kills the tumor cells. A search revealed similar products...

ABBV-399 (generic name: telisotuzumab vedotin) received accelerated approval from the US FDA in May 2025.

It is approved for marketing use for the treatment of advanced/metastatic non-squamous lesions with high c-Met protein expression who have previously received systemic therapy.

Adult patients with non-small cell lung cancer. To date, the cumulative R&D investment in projects related to injectable SHR-1826 is approximately...

125.5 million yuan.

III. Risk Warning

According to the "Notice of the National Medical Products Administration on Issuing the <Procedures for Review of Breakthrough Therapy Drugs (Trial)>" and other relevant documents...

Announcement No. 82 of 2020 (hereinafter referred to as "Announcement"), the Center for Drug Evaluation (CDE) reviews drugs included in the Breakthrough Therapy Program.

Prioritize resource allocation for communication and exchange, strengthen guidance, and promote drug development. Drug development is susceptible to technological and other factors.

The drug market is subject to various factors, including approval processes, policies, and the future competitive landscape.

Uncertainty and risk. Investors are advised to make prudent decisions and be aware of investment risks. The company will comply with relevant national regulations.

In accordance with relevant regulations, we will actively promote the aforementioned R&D projects and fulfill our obligation to disclose information on the subsequent progress of the projects in a timely manner.

This is to announce.

Board of Directors of Jiangsu Hengrui Medicine Co., Ltd.

January 12, 2026

[1]. Cancer incidence and mortality rates in China, 2022, *Journal of the National Cancer Center*