Jiangsu Hengrui Pharmaceuticals Co., Ltd.
江蘇恒瑞醫藥股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 1276)

OVERSEAS REGULATORY ANNOUNCEMENT

This announcement is made pursuant to the disclosure requirements under Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

According to the relevant regulations of the People's Republic of China, Jiangsu Hengrui Pharmaceuticals Co., Ltd. (the "**Company**") had published an announcement on the website of the Shanghai Stock Exchange (www.sse.com.cn). The following is a translation of the abovementioned announcement solely for reference only. Should there be any discrepancies, the Chinese version will prevail.

By order of the Board
Jiangsu Hengrui Pharmaceuticals Co., Ltd.
江蘇恒瑞醫藥股份有限公司
Mr. Sun Piaoyang
Chairman

Shanghai, PRC
May 29, 2025

As at the date of this announcement, the Board comprises: (i) Mr. Sun Piaoyang, Mr. Dai Hongbin, Ms. Feng Ji, Mr. Zhang Lianshan, Mr. Jiang Frank Ningjun and Mr. Sun Jieping as executive Directors; (ii) Ms. Guo Congzhao as non-executive Director; and (iii) Mr. Dong Jiahong, Mr. Zeng Qingsheng, Mr. Sun Jinyun and Mr. Chow Kyan Mervyn as independent non-executive Directors.

Jiangsu Hengrui Pharmaceuticals Co., Ltd. Announcement in Relation to the Approval for Drug Registration

The board of directors of the Company and all directors warrant that this announcement does not contain any false information, misleading statement or material omission, and accept legal liability for the truthfulness, accuracy and completeness of the contents herein.

Recently, Suzhou Suncadia Biopharmaceuticals Co., Ltd. (蘇州盛迪亞生物醫藥有限公司), a subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江蘇恒瑞醫藥股份有限公司) (the "Company"), received a notice from the National Medical Products Administration (NMPA). The NMPA conditionally approves the Company's self-developed Class 1 innovative drug, Trastuzumab Rezetecan for Injection (SHR-A1811), for marketing. It is indicated for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) who have HER2 (ERBB2) activating mutations and have received at least one prior systemic therapy. This is the first self-developed antibody drug conjugate (ADC) in China that has been approved for patients with HER2-mutant NSCLC. The relevant information is hereby announced as follows:

I. Basic Information of the Drug

Common name of drug: Trastuzumab Rezetecan for Injection

Dosage Form: Injection

Specification: 0.1g/ bottle

Registered Category: Class 1 therapeutic biological product

Application Number: CXSS2400099

Prescription/Non-prescription Drug: Prescription Drug

Approved indication: This product, as a monotherapy, is indicated for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) who have HER2 (ERBB2) activating mutations and have received at least one prior systemic therapy.

II. Other Information of the Drug

In the driver gene mutation landscape of non-small cell lung cancer (NSCLC), HER2 mutation represents a rare yet clinically challenging subtype, accounting for 2%-4% of cases. Although HER2 mutation is a well-defined driver gene, traditional second-line treatment options such as chemotherapy, immunotherapy, and currently approved pan-HER tyrosine kinase inhibitors (TKIs) have shown limited efficacy, with objective response rates (ORRs) generally below 30% and median progression-free survival (mPFS) of approximately only 6 months[1-5]. Patients face a long-term dilemma of lacking effective treatment options.

Trastuzumab Rezetecan for Injection is the Company's self-developed HER2-targeted ADC. After binding to tumor cells and being internalized, Trastuzumab Rezetecan releases its toxin through protease cleavage within tumor cell lysosomes, inducing cell cycle arrest, ultimately triggering tumor cell apoptosis. The released toxin has high membrane permeability, enabling a bystander killing effect, which further enhances the antitumor efficacy. This approval is based on the pivotal HORIZON-Lung study led by Professor Shun Lu of Shanghai Chest Hospital. The latest data from the study shows that in previously treated patients with HER2-mutant advanced or metastatic NSCLC, Trastuzumab Rezetecan had a median follow-up of 14.2 months. The objective response rate (ORR) assessed by the Independent Review Committee (IRC) reached 74.5%, setting a new benchmark for global comparable studies[6, 7]. The median PFS (mPFS) was 11.5 months, with a 12-month PFS rate of 48.6%. This study was successfully published in The Lancet Oncology in February 2025[6] and made a significant appearance with its updated data at the 2025 Annual Meeting of American Association for Cancer Research (AACR), sparking an

extensive attention from scholars in the field[7]. In the field of anti-HER2 therapy, the therapeutic potential of Trastuzumab Rezetecan is being actively exploring in first-line treatment for patients with HER2-mutant NSCLC, as well as in populations with HER2 amplification and overexpression. In addition to lung cancer, Trastuzumab Rezetecan has also achieved significant progress in other cancer types. At present, it has been granted Breakthrough Therapy Designation by the NMPA for eight indications, including lung cancer, breast cancer, colorectal cancer, gastric or gastroesophageal junction adenocarcinoma, biliary tract cancer, cervical cancer and epithelial ovarian cancer, and fallopian tube cancer or primary peritoneal cancer. It is expected to benefit a broader patient population in the future.

According to available information, similar products already marketed abroad include Ado-trastuzumab emtansine (brand name Kadcyla) and Fam-trastuzumab deruxtecan (brand name Enhertu). Kadcyla was developed by Roche and was imported and launched in China in 2019. Enhertu was jointly developed by AstraZeneca and Daiichi Sankyo and was imported and launched in China in 2023. In addition, Disitamab vedotin (brand name Aidixi), developed by RemeGen, was approved for marketing in China in 2021. According to the EvaluatePharma database, the combined global sales of Kadcyla, Enhertu, and Aidixi in 2024 amounted to approximately USD 6.557 billion. To date, the total accumulated R&D investment in the Trastuzumab Rezetecan for Injection project is approximately RMB 1,170.07 million.

III. Risk Warning

The Company places great importance on drug R&D, and strictly controls the quality and safety throughout the processes of drug R&D, manufacture, and sales. However, post-approval production and sales may be subject to uncertainties. Investors are kindly advised to make prudent decisions and pay attention to investment risks.

Notice is hereby given.

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

May 29, 2025

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[5] Chu X, Qiang H, Xie M, et al. Cancer Immunol Immunother. 2022;71(7):1625-1631.
[6] Li Z, Wang Y, Sun YP, Si W, Lu S. The Lancet Oncology 2025.
[7] Lu S, et al. AACR 2025.