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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
August 6, 2026

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. Lou Liguang, 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 notification from the National Medical Products Administration (the “NMPA”) that the Company’s third indication for trastuzumab rezetecan for injection has been approved for marketing in China, making it the first anti-HER2 product approved for the treatment of colorectal cancer in the country. The relevant information is hereby announced as follows:

I. Basic Information of the Drug

Drug name: Trastuzumab Rezetecan for Injection

Dosage form: Injection

Strength: 0.1 g/vial

Registration category: Class 2.2 therapeutic biological product

Acceptance no.: CXSS2600018

Prescription/over-the-counter drug: Prescription drug

Approved indication: For the treatment of adult patients with HER2-positive colorectal cancer who have failed prior treatment with oxaliplatin, fluorouracil and irinotecan.

II. The Approved Indications of the Drug

The Company's trastuzumab rezetecan for injection has been approved for two indications in China, namely: for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring activating HER2 (ERBB2) mutations who have previously received at least one line of systemic therapy; and for the treatment of adult patients with locally advanced or metastatic HER2-positive breast cancer who have previously received one or more lines of anti-HER2 therapy.

III. Other Information of the Drug

Colorectal cancer is one of the most common malignant tumors worldwide and poses a serious threat to human health. In colorectal cancer, the incidence of HER2 amplification is 5.8%, the incidence of overexpression is 5% and the incidence of mutation is 2% ^[1]. Conventional targeted therapies and chemotherapeutic agents have shown limited efficacy in HER2-positive colorectal cancer. In particular, patients with advanced colorectal cancer who have failed treatment with oxaliplatin, irinotecan and fluorouracil commonly face multiple challenges, including short overall survival duration and limited treatment options. HER2 is an important target in oncology, and anti-HER2 therapies have been widely used in breast cancer and gastric cancer. However, no anti-HER2 therapy had previously been approved for colorectal cancer in China, representing a significant unmet medical need among patients. The approval of this new indication for trastuzumab rezetecan addresses the long-standing lack of high-level evidence-based medical proof for patients with HER2-positive colorectal cancer. Currently, trastuzumab rezetecan has been recommended by the CSCO Guidelines for the Diagnosis and Treatment of Colorectal Cancer (2026 Edition) for later-line treatment of patients with HER2-positive colorectal cancer ^[2].

Trastuzumab rezetecan for injection is a HER2-targeted antibody-drug conjugate (ADC) independently developed by the Company. It binds to HER2-expressing tumor cells and is internalized. Within the tumor cell lysosomes, the toxin is released through protease cleavage, inducing cell cycle arrest and thereby triggering tumor cell apoptosis. The released toxin has high membrane permeability and can exert a bystander killing effect that further enhances anti-tumor efficacy. The approval was primarily based on

the randomized, open-label, active-controlled, multicenter, Phase III HORIZON-CRC01 (SHR-A1811-III-309) study, which was jointly led by Professor Li Jin from Shanghai GoBroad Cancer Hospital Affiliated with China Pharmaceutical University and Professor Yuan Ying from the Second Affiliated Hospital of Zhejiang University School of Medicine. The study met its primary endpoint, and its pivotal data were presented as an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting ^[3].

Currently, 11 indications of trastuzumab rezetecan have been included in the Breakthrough Therapy Designation list, covering non-small cell lung cancer, breast cancer, gastric or gastro-oesophageal junction adenocarcinoma, colorectal cancer, biliary tract cancer, gynaecological malignancies and other cancers. In addition to the Company's trastuzumab rezetecan for injection, other similar products marketed in China include ado-trastuzumab emtansine developed by Roche, fam-trastuzumab deruxtecan co-developed by AstraZeneca and Daiichi Sankyo, disitamab vedotin developed by RemeGen and trastuzumab botidotin developed by Kelun-Biotech. According to the EvaluatePharma database, the total global sales of the above similar products in 2025 amounted to approximately USD8.157 billion. As of now, the cumulative R&D investment in projects related to trastuzumab rezetecan for injection is approximately RMB2,144.20 million (unaudited).

IV. 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.

August 6, 2026

[1] Oh DY, Bang YJ. HER2-targeted therapies - a role beyond breast cancer. *Nat Rev Clin Oncol*. 2020;17(1):33-48.

[2] CSCO Guidelines for the Diagnosis and Treatment of Colorectal Cancer (2026 Edition).

[3] Li J, Yuan Y, Liu T, et al. Phase 3 trial of trastuzumab rezetecan vs standard of care (SOC) for chemotherapy-refractory, HER2-positive, advanced colorectal cancer (CRC)[J]. 2026 ASCO. Abs #3505.