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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
October 24, 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, Shandong Suncadia Medicine Co., Ltd. (山東盛迪醫藥有限公司), 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). Approval is granted for the marketing of the company's Henagliflozin Proline, Retagliptin Phosphate and Metformin Hydrochloride Sustained-release Tablets（I）,（II） (HR20031). This product is the first oral triple fixed-dose combination independently developed in China. The relevant information is hereby announced as follows:

## I. Basic Information of the Drug

Common name of drug: Henagliflozin Proline, Retagliptin Phosphate and Metformin Hydrochloride Sustained-release Tablets（I）,（II）

Dosage Form: Tablets

Specification: 5/50/750mg, 10/100/1000mg

Registered Category: Class 2.3 chemical drug

Application Number: CXHS2300099、CXHS2300100

Prescription/Non-prescription Drug: Prescription Drug

Approved indication: This product is indicated as an adjunct to diet and exercise

to improve glycemic control in adults with type 2 diabetes who have inadequate glycemic control on metformin monotherapy.

**II. Other Information of the Drug**

Currently, diabetes has become the third most serious chronic disease endangering human health, following cancer and cardiovascular and cerebrovascular diseases. According to the International Diabetes Federation (IDF) 11th edition data, the diabetes prevalence rate among Chinese adults (20–79 years) has reached 13.79%, with 148 million patients, making China the country with the highest number of diabetes cases globally [1]. Furthermore, patients with type 2 diabetes (T2DM) have poor medication adherence, with glycemic control rate at only 50.1% [2]. HR20031 is a fixed-dose combination containing Henagliflozin proline, Retagliptin phosphate, and Metformin hydrochloride, which is expected to improve glycemic control through three complementary mechanisms of action. This product is indicated as once-daily oral therapy for adults with inadequately controlled T2DM on metformin monotherapy. It simplifies the treatment regimen through reduced pill burden, potentially improving medication adherence. Currently marketed triple fixed-dose combinations with identical ingredients include TRIJARDY® XR (empagliflozin/linagliptin/metformin hydrochloride sustained-release tablets) of Boehringer Ingelheim-Lilly Diabetes Alliance; no therapeutically equivalent competitors have been approved for marketing in China. To date, the total accumulated R&D investment of the HR20031 project is approximately RMB 189.24 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.

October 24, 2025

[1]. IDF Diabetes Atlas 11th edition. https://diabetesatlas.org/

[2]. Wang L, Peng W, Zhao Z, et al. Prevalence and treatment of diabetes in China, 2013-2018[J]. JAMA, 2021, 326(24):2498-2506.

DOI: 10.1001/jama.2021.22208.