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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
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.

Stock code:600276

Stock abbreviation:Hengrui Pharma

No.: Lin 2025-087

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, Fujian Shengdi Pharmaceutical Co., Ltd. (福建盛迪醫藥有限公司), 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). The NMPA approves the Company’s self-developed Class 1 innovative drug, Fosrolapitant and Palonosetron Hydrochloride for Injection (HR20013), for marketing. It is indicated for the prevention of acute and delayed nausea and vomiting caused by highly emetogenic chemotherapy (HEC) in adults. This product is China’s first ultra-long-acting original compound antiemetic injection. The relevant information is hereby announced as follows:

I. Basic Information of the Drug

Common name of drug: Fosrolapitant and Palonosetron Hydrochloride for Injection

Dosage Form: Injection

Specification: Fosrolapitant 218mg and palonosetron hydrochloride 0.25mg (calculated based on $C_{19}H_{24}N_2O$)

Registered Category: Class 1 chemical drug

Application Number: CXHS2300113

Prescription/Non-prescription Drug: Prescription Drug

Approved indication: This product is indicated for the prevention of acute and delayed nausea and vomiting caused by highly emetogenic chemotherapy (HEC) in adults.

II. Other Information of the Drug

With the continuous improvement of tumor diagnosis and treatment levels, patients' survival time has been extended. At the same time, improving patients' quality of life during tumor treatment and ensuring the smooth and complete delivery of their tumor treatment have become increasingly important focuses for both medical professionals and patients. Chemotherapy-induced nausea and vomiting (CINV) is a common adverse reaction during tumor treatment. In HEC represented by cisplatin, the incidence of acute vomiting exceeds 90%, and the incidence of delayed nausea and vomiting exceeds 50%.^[1,2] The occurrence of CINV reduces patients' quality of life and treatment compliance, thereby affecting the therapeutic benefits. Studies show that 32% of patients interrupt or discontinue chemotherapy due to CINV.^[3] Therefore, proactive prevention of CINV is of vital importance in the management of cancer patients.

At present, the clinical management of HEC-related CINV primarily relies on triple or quadruple drug regimens based on neurokinin-1 (NK-1) receptor antagonists and 5-hydroxytryptamine 3 (5-HT₃) receptor antagonists. Due to the relatively short half-life of available drugs, it has long been difficult to cover the entire risk period of CINV with a single dose. Prolonged and repeated administration is required, making it difficult to ensure standardized treatment.^[4,5] Therefore, there is an urgent clinical need for more long-lasting and convenient comprehensive management strategies.

Fosrolapitant and Palonosetron Hydrochloride for Injection is a combination product that simultaneously targets both the NK-1 receptor and 5-HT₃ receptor pathways to inhibit the vomiting reflex. Leveraging on an ultra-long half-life of nearly 8 days, it only requires a single dose per chemotherapy cycle to cover the acute, delayed, and extended delayed phases of CINV simultaneously.^[1] According to available information, similar NK-1 receptor/5-HT₃ receptor antagonist combination

products marketed abroad include Helsinn Healthcare's AKYNZEO intravenous injection (fosnetupitant/palonosetron) and oral capsule (netupitant/palonosetron). At present, AKYNZEO oral capsule (netupitant/palonosetron) has been marketed in China, while no similar injectable formulations have been approved for marketing yet. To date, the total accumulated R&D investment in the Fosrolapitant and Palonosetron Hydrochloride for Injection project is approximately RMB 182.16 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

- [1]. Hospital Pharmacy Committee of the Chinese Pharmaceutical Association, Guidelines for the Pharmacological Prevention and Treatment of Chemotherapy-Induced Nausea and Vomiting [J]. Chinese Journal of Hospital Pharmacy. 2022;42(5): 457–473.
- [2]. Committee of Neoplastic Supportive-Care, China Anti-Cancer Association. Chinese Expert Consensus on Prevention and Treatment of Delayed Nausea and Vomiting [J]. Chinese Clinical Oncology. 2023;28(5): 442–458.
- [3]. Van Laar ES, Desai JM, Jatoi A. Professional educational needs for chemotherapy-induced nausea and vomiting (CINV): multinational survey results from 2388 health care providers. Support Care Cancer. 2015 Jan;23(1):151-7.
- [4]. Grunberg SM, Koeller JM. Palonosetron: a unique 5-HT3-receptor antagonist for the prevention of chemotherapy-induced emesis. Expert Opin Pharmacother. 2003 Dec;4(12):2297-303.
- [5]. Li HT, He CX, Zhou H, Wang HX. Pharmacokinetic Study of Single-dose Fosaprepitant Dimeglumine (150 mg) in Healthy Chinese Volunteers [J]. Chinese Journal of General Practice, 2023,21(11):1841-1844.