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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
June 16, 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, 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 (hereinafter referred to as “NMPA”) that a new indication for dalpiciclib isethionate tablets, a CDK4/6 inhibitor self-developed by the Company, has been approved. The relevant information is hereby announced as follows:

I. Basic Information of the Drug

Drug Name: Dalpiciclib Isethionate Tablets

Dosage Form: Tablets

Strength: 50 mg, 125 mg

Registered Category: Class 2.4 Chemical Drug

Acceptance No.: CXHS2500044, CXHS2500045

Prescription/Non-prescription Drug: Prescription Drug

Approved Indication: This product, in combination with endocrine therapy, is indicated for adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer at high risk of recurrence.

II. The Approved Indications of the Drug

Dalpiciclib was first approved for marketing in China in 2021 and has to date been approved for two indications. This product is indicated for patients with HR-positive,

HER2-negative locally advanced or metastatic breast cancer — 1. in combination with an aromatase inhibitor as initial endocrine therapy; and 2. in combination with fulvestrant for patients whose disease has progressed following prior endocrine therapy.

III. Other Information of the Drug

Breast cancer ranks among the leading malignancies among women worldwide in terms of incidence and mortality¹, posing a serious threat to female health. The Statistical Analysis Report of Cancer Incidence and Mortality Data in China (2024) shows that the annual number of new breast cancer cases among women in China is 376,000². HR+/HER2- breast cancer is the most common molecular subtype in clinical practice, accounting for approximately 70% of all cases³. Studies have demonstrated that, even with standard postoperative adjuvant endocrine therapy, some patients with HR+/HER2- early breast cancer remain at risk of recurrence for up to 20 years⁴. Previously, the evidence supporting the use of CDK4/6 inhibitors available in China for adjuvant treatment of HR+/HER2- early breast cancer relied primarily on data from Western populations. However, Chinese patients with breast cancer differ from those outside China in genetic background, biological characteristics, and clinical diagnosis and treatment. For example, the age at onset is relatively younger, with a median age at diagnosis of only approximately 45–49 years⁵, and the risk of recurrence is higher. Moreover, 62.9% of women are diagnosed before menopause⁶, making treatment more challenging. There is an urgent need to explore treatment regimens that are more closely aligned with the diagnosis and treatment landscape for Chinese patients with HR+/HER2- early breast cancer.

Dalpiciclib isethionate tablets are an orally administered, high-efficacy, selective small-molecule CDK4/6 inhibitor independently developed by the Company. The approval of this new indication is based on positive results from a large, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial (study code: DAWNA-A)^{7, 8}. The DAWNA-A study is the first adjuvant Phase 3 clinical study in high-risk patients with early breast cancer conducted in a 100% Chinese population to achieve positive results. A total of 5,274 Chinese patients with stage II–III HR+/HER2-high-risk early breast cancer were enrolled. Approximately 60% were

premenopausal/perimenopausal, closely reflecting the epidemiologic characteristics of breast cancer in the Chinese population. In the study results, the first interim analysis showed that, at a median follow-up of 20.3 months, dalpiciclib in combination with endocrine therapy significantly improved invasive disease-free survival (IDFS) versus placebo; the absolute 2-year IDFS benefit was 4.5% (94.7% vs. 90.2%), and the risk of disease progression or death was reduced by 44.5% (HR = 0.56, 95% CI: 0.43–0.71, $P < 0.0001$)⁷. Updated results from the second interim analysis showed that, at a median follow-up of 27.0 months, the IDFS benefit with dalpiciclib in combination with endocrine therapy was sustained; the absolute 3-year IDFS benefit was 3.2% (90.6% vs. 87.4%), and the risk of disease recurrence or death was significantly reduced by 40.0% (HR = 0.60, 95% CI: 0.49–0.74)¹⁰. The IDFS benefit was consistent across subgroups². Disease-free survival (DFS) and distant disease-free survival (DDFS) were also significantly improved⁸.

The approval of this indication for dalpiciclib marks an expansion of its clinical development strategy in breast cancer from advanced disease to early adjuvant therapy and fills the gap in the adjuvant treatment field for HR+/HER2- early breast cancer for independently developed CDK4/6 inhibitors in China. Dalpiciclib in combination with endocrine therapy as adjuvant treatment for HR+/HER2- high-risk early breast cancer has been formally included in the 2026 edition of the “Chinese Society of Clinical Oncology (CSCO) Guidelines for the Diagnosis and Treatment of Breast Cancer” and the 2026 edition of the “China Anti-Cancer Association Guidelines and Standards for the Diagnosis and Treatment of Breast Cancer.”

Currently, multiple products of the same class have been approved and marketed in China and abroad, including Pfizer’s palbociclib (brand name: Ibrance), Novartis’s ribociclib (brand name: Kisqali), and Eli Lilly’s abemaciclib (brand name: Verzenio). Among these, the only CDK4/6 inhibitors approved in China for the indication of adjuvant treatment of early breast cancer are ribociclib and abemaciclib. According to the EvaluatePharma database, the total global sales of similar products in 2025 amounted to approximately USD 14.637 billion. As of the date hereof, the cumulative R&D investment in projects related to dalpiciclib isethionate tablets is approximately

RMB 1,287.02 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.

June 16, 2026

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4. Breast Cancer Expert Committee of the National Cancer Quality Control Center, Professional Committee of Clinical Research on Antitumor Drugs of the China Anti-Cancer Association, Breast Cancer Professional Committee of the China Anti-Cancer Association. Expert consensus on recurrence risk and clinical management of HR+/HER-2- early breast cancer (2025 edition). *Chinese Journal of Oncology*, 2025, 47(7): 599-616.
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