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Xuanzhu Biopharmaceutical Co., Ltd.
軒竹生物科技股份有限公司

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

(Stock Code: 2575)

VOLUNTARY ANNOUNCEMENT MARKETING APPROVAL FOR THE THIRD INDICATION OF XUANYUENING (BIREOCICLIB TABLETS) FOR THE FIRST-LINE TREATMENT OF HR+/HER2- ADVANCED BREAST CANCER GRANTED BY THE NMPA

The board of directors (the "**Board**") of Xuanzhu Biopharmaceutical Co., Ltd. (the "**Company**", together with its subsidiaries, collectively the "**Group**") is pleased to announce that the marketing approval for the new indication regarding the supplemental New Drug Application ("**sNDA**") of the Company's independently developed innovative drug, Bireociclib Tablets (brand name: Xuanyuening) in combination with aromatase inhibitor ("**AI**") for the treatment of first-line treatment of HR+/HER2- advanced breast cancer has been granted by the National Medical Products Administration of China ("**NMPA**"). This marks the third indication approved in China following the approvals for combined use with fulvestrant and as an indication of single drug treatment. Consequently, Bireociclib has become the first and only drug in China covering the entire spectrum of first-line, second-line, and later-line treatments of HR+/HER2- advanced breast cancer. This expansion of the approved indication to include first-line treatment of HR+/HER2- advanced breast cancer significantly broadens patient coverage, effectively enhances the clinical value and drug accessibility of the product, and provides robust support for its future sales growth.

Breast cancer is the most diagnosed malignant tumor among women worldwide. Reports from China Insights Consultancy indicated that the number of new breast cancer cases in China increased from 322,200 in 2018 to 374,700 in 2024 and is expected to reach 435,000 by 2032. HR+/HER2- breast cancer is the most prevalent subtype in China, accounting for approximately 75% of total cases. Among HR+/HER2- breast cancer patients, about 30% were diagnosed with advanced breast cancer. In China, CDK4/6 inhibitors combined with endocrine therapy for HR+/HER2- advanced breast cancer have become the standard first-line treatment, and the market size for CDK4/6 inhibitors in China is expected to reach RMB13 billion by 2032.

The approval of this new indication is mainly based on the data results from the BRIGHT-3 study (NCT05257395). The BRIGHT-3 study is a randomized, double-blind Phase III clinical trial conducted across 58 centers in China, aiming to evaluate the efficacy and safety of Bireociclib in combination with letrozole or anastrozole for the first-line treatment of HR+/HER2- advanced breast cancer. Prior to that, the research results of BRIGHT-3 were first published in the European Society for Medical Oncology ("**ESMO 2025**"). Results of this interim analysis showed that, in terms of efficacy, the median Progression-Free Survival (mPFS) for the Bireociclib group assessed by both the investigators and the independent review committee had not been reached, compared to 18.43 months and 19.55 months for the control group, respectively. The fact that mPFS has not been reached suggests that more patients in the Bireociclib group have not yet experienced disease progression, reflecting its durable efficacy advantage. Compared with endocrine therapy combined with placebo, the Bireociclib regimen can reduce the risk of disease progression or death by 47%. Notably, in patients with liver metastases (specifically with a poor prognosis), the disease progression or death risk was significantly reduced by 64%, demonstrating its outstanding potential in the refractory population. In the intention-to-treat population, the objective response rate (ORR) in the Bireociclib group reached 63.5%, significantly superior to 42.5% in the control group. In terms of safety, common adverse events of the Bireociclib combination regimen (such as diarrhea and neutropenia) were mostly Grade 1–2, which can be effectively managed through supportive care or dose adjustment, with overall controllable safety.

ABOUT BIREOCICLIB

Bireociclib Tablets (brand name: Xuanyuening), as the first approved CDK2/4/6 inhibitor in China, possesses a unique multi-target synergistic mechanism of action, offering advantages such as potent inhibition of tumor cell proliferation and a significant reduction in hematological toxicity commonly associated with traditional CDK4/6 inhibitors. Bireociclib was approved by the National Medical Products Administration in May 2025, for use in combination with Fulvestrant for the treatment of patients with hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) ("**HR+/HER2-**") advanced or metastatic breast cancer whose disease has progressed after prior endocrine therapy, and as a monotherapy for HR+/HER2- advanced or metastatic breast cancer patients who have progressed after receiving two or more lines of endocrine therapies and one chemotherapy in the metastatic stage, making it the first and only CDK2/4/6 inhibitor in China approved for a monotherapy indication. PharmCube statistics indicated that Bireociclib also ranked first in the global CDK2/4/6 inhibitor market. In December 2025, the two approved indications of Bireociclib Tablets have been included in the National Reimbursement Drug List for Basic Medical Insurance, Maternity Insurance and Work-Related Injury Insurance (2025), effective on January 1, 2026.

This announcement is made by the Company on a voluntary basis to update the investors of the Group's latest business development, and does not constitute, and is not intended to be, an advertisement regarding the use of any medicine, surgical appliance, treatment or orally consumed product.

By order of the Board
Xuanzhu Biopharmaceutical Co., Ltd
Ms. Xu Yanjun
Chairperson of the Board and executive Director

Hong Kong, March 3, 2026

As of the date of this announcement, the Board comprises (i) Ms. Xu Yanjun, Dr. Li Jia Kui and Dr. Shih Cheng-Kon as executive Directors; (ii) Ms. Li Huiying, Mr. Yu Lifeng and Ms. Chen Yanling as non-executive Directors; and (iii) Mr. Liu Shuo, Ms. Wang Yu and Mr. Fan Chi Chiu as independent non-executive Directors.