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
ANNOUNCEMENT OF PHASE III CLINICAL STUDY DATA OF BIREOCICLIB FOR FIRST-LINE TREATMENT OF HR+/HER2 – ADVANCED BREAST CANCER AT ESMO 2025

The board of directors (the "**Board**") of Xuanzhu Biopharmaceutical Co., Ltd. (the "**Company**" or "**Xuanzhu Biopharmaceutical**", together with its subsidiaries, collectively referred to as the "**Group**") hereby announces that the interim analysis results of the Phase III clinical study (BRIGHT-3) of Bireociclib in combination with letrozole or anastrozole for the first-line treatment of HR+/HER2 – advanced breast cancer were presented in the form of a poster at the European Society for Medical Oncology 2025 ("**ESMO 2025**") in Germany on October 20, 2025, local time.

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. A total of 397 patients with HR+/HER2 – advanced breast cancer were enrolled in this study. In the intention-to-treat population, 55.7% of the patients had visceral metastases, and 41.3% were new cases of advanced breast cancers.

As of January 10, 2025, the median follow-up time was 20.7 months. The results of this interim analysis showed that, as for 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%. Specifically, as for patients with liver metastases (who have a poor prognosis), the disease 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.

Based on the interim data of the BRIGHT-3 study, the National Medical Products Administration of China (NMPA) officially accepted the New Drug Application (NDA) for Bireociclib in combination with aromatase inhibitor (AI) for the treatment of HR+/HER2 – advanced breast cancer on May 14, 2025.

ABOUT BIREOCICLIB

Bireociclib Tablets (trade name: Xuan Yuen Ning), as a novel CDK2/4/6 inhibitor, 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 of the PRC on May 13, 2025, for use in combination with Fulvestrant for the treatment of patients who have progressed after prior endocrine therapy, and as a monotherapy for 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 CDK4/6 inhibitor in the PRC approved for a monotherapy indication.

ABOUT XUANZHU BIOPHARMACEUTICAL

Xuanzhu Biopharmaceutical is the innovative drug subsidiary of Sihuan Pharmaceutical Holdings Group Ltd. ("**Sihuan Pharmaceutical**"). It is an innovative pharmaceutical company with roots in China and a global perspective, focusing on major diseases such as digestion, oncology and non-alcoholic steatohepatitis, and is committed to the research and development, production and commercialization of class 1 drugs with core proprietary intellectual property rights. The Company has a first-class R&D team, all core personnel have years of experience in new drug research and development. The Company has two R&D platforms: small molecule chemistry and large molecule biologics. The dual engines drive the Company's innovation and development, forming a product pipeline that covers small molecule chemistry, large molecule biopharmaceuticals, antibody drug conjugates (ADCs) and other types of products. With a focus on unmet major clinical needs, the company is committed to developing into a first-class innovative pharmaceutical company with independent research and development, production, and sales capabilities.

This announcement is being made by the Company on a voluntary basis to update the investors on 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, October 22, 2025

As of the date of this announcement, the board of directors of the Company 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.