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# **FOSUN PHARMA** **复星医药**

上海復星醫藥(集團)股份有限公司

**Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\***

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

(Stock Code: 02196)

## **OVERSEAS REGULATORY ANNOUNCEMENT**

This announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. The following sets out the “Announcement in Relation to the Approval of Drug Clinical Trial of a Subsidiary” published by Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\* (the “**Company**”) on the website of the Shanghai Stock Exchange, for your reference only. The following is a translation of the abovementioned announcement solely for the purpose of providing information. Should there be any discrepancies, the Chinese version will prevail.

By order of the Board

**Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\***

**Wu Yifang**

*Chairman*

Shanghai, the PRC

29 February 2024

*As at the date of this announcement, the executive directors of the Company are Mr. Wu Yifang, Mr. Wang Kexin, Ms. Guan Xiaohui and Mr. Wen Deyong; the non-executive directors of the Company are Mr. Chen Qiyu, Mr. Yao Fang, Mr. Xu Xiaoliang and Mr. Pan Donghui; and the independent non-executive directors of the Company are Ms. Li Ling, Mr. Tang Guliang, Mr. Wang Quandi and Mr. Yu Tze Shan Hailson.*

\* *for identification purposes only*

# **Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\***

## **Announcement in Relation to the Approval of Drug Clinical Trial of a Subsidiary**

**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 contained.**

### **I. Overview**

Shanghai Fosun Pharmaceutical Industry Development Co., Ltd.\* (上海復星醫藥產業發展有限公司) (“**Fosun Pharmaceutical Industry**”) and Fochon Pharmaceuticals, Ltd.\* (重慶復創醫藥研究有限公司) (“**Fochon Pharma**”), both subsidiaries of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\* (上海復星醫藥(集團)股份有限公司) (the “**Company**” and, together with its subsidiaries/units, the “**Group**”, the same applies below) recently received the approval from the National Medical Products Administration of the People’s Republic of China (“**NMPA**”) for clinical trial of FCN-338 tablet and FCN-647 tablet in combination for the treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (the “**Treatment Plan**”). Fosun Pharmaceutical Industry and Fochon Pharma intend to commence the Phase II clinical trial of the Treatment Plan in China (excluding Hong Kong, Macau and Taiwan regions for the purpose of this announcement, the same applies below) when the conditions are fulfilled.

### **II. Basic Information and Research Progress on the Investigational New Drugs Involved in the Treatment Plan**

The FCN-338 tablet involved in the Treatment Plan is a Bcl-2 selective small molecule inhibitor independently developed by the Group, which are intended to be used in the treatment of hematological malignancies. The FCN-647 tablet is a BTK selective small

molecule inhibitor independently developed by the Group, which are intended to be used in the treatment of hematological malignancies. As at the date of the announcement, the progress of clinical trials of these new investigational drugs are as follows:

1. The Phase I clinicals trial of FCN-338 tablet are conducted in China and the United States, respectively, for the treatment of hematological malignancies and relapsed or refractory B-cell lymphoma, and the Phase II clinical trial of the FCN-338 in combination with azacitidine or chemotherapy for the treatment of myeloid blood malignancies is conducted in China. A Phase II clinical trial application of FCN-338 tablet in combination with dexamethasone for the treatment of systemic light chain amyloidosis was approved in January 2024 by NMPA.

2. The Phase I clinicals trial of FCN-647 tablet is conducted in China for the treatment in relapsed or refractory B-cell lymphom.

As of January 2024, the Group has invested approximately RMB0.19 million (unaudited; excluding single drugs) in total in the research and development (the “R&D”) of the Treatment Plan at current stage.

As at the date of this announcement, a similar combination Treatment Plan using Venetoclax in combination with Ibrutinib for the treatment of first-line chronic lymphocytic leukemia has been approved for marketing worldwide. According to the latest information from IQVIA MIDAS<sup>TM1</sup>, the sales of Venetoclax and Ibrutinib respectively amounted to approximately US\$2,030 million and US\$6,493 million worldwide in 2022.

### **III. Risk Warning**

As required by the relevant laws and regulations in China, the investigational new drugs FCN-338 tablets and FCN-647 tablets involved in the Treatment Plan are still at the clinical trial stage and subject to undergo a series of clinical studies and be approved by the national drug review authority before they can be launched. There are certain risks in the R&D of new drugs based on our experience. For example, clinical trials may be terminated due to issues such as safety and/or efficacy.

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<sup>1</sup> Data provided by IQVIA, a provider of professional medical and health information and strategic consultation service in the world.

The R&D and launch of new drugs is a long-term task involving many uncertainties.  
Investors should take note of the investment risks.

Announcement is hereby made.

Board of Directors of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\*

29 February 2024

*\*For identification purpose only*