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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 for Drug Clinical Trial by 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.\***

**Chen Qiyu**

*Chairman*

Shanghai, the People's Republic of China

16 July 2020

*As at the date of this announcement, the executive directors of the Company are Mr. Chen Qiyu, Mr. Yao Fang and Mr. Wu Yifang; the non-executive directors of the Company are Mr. Xu Xiaoliang, Mr. Gong Ping and Mr. Pan Donghui; and the independent non-executive directors of the Company are Mr. Jiang Xian, Dr. Wong Tin Yau Kelvin, Ms. Li Ling and Mr. Tang Guliang.*

\* *for identification purposes only*

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## **Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\* Announcement in Relation to the Approval for Drug Clinical Trial by 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 severally and jointly accept full responsibility for the truthfulness, accuracy and completeness of the contents contained herein.**

### **I. Overview**

Recently, Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd.\* (上海復星醫藥產業發展有限公司) (“Fosun Pharmaceutical Industrial”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\* (the “**Company**”), has received the approval for clinical trial of the licensed COVID-19 mRNA vaccine product candidate BNT162b1 (the “**Vaccine**”) by the National Medical Products Administration (the “**NMPA**”). Fosun Pharmaceutical Industrial plans to initiate a phase I clinical trial of the Vaccine in the PRC (excluding Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan region, hereinafter the same) as soon as possible once it is ready.

## **II. Research Progress of the Vaccine**

In March 2020, Fosun Pharmaceutical Industrial has obtained the license granted by a German company BioNTech SE (“**BioNTech**”) to exclusively develop and commercialize its vaccine products developed based on BioNTech’s proprietary mRNA technology platform targeting COVID-19 in the Region (i.e. Chinese Mainland, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan region, hereinafter the same). BioNTech is the rights holder of the Vaccine in the Region.

The Vaccine candidate is a prophylactic biological product, aiming at the precaution of COVID-19 for persons who aged 18 or above.

As at the date of this announcement, the Vaccine is in phase I clinical trial in Germany and the United States, respectively. There is still no mRNA-based prophylactic vaccine has yet been approved for launch in the world.

As at the end of June 2020, the cumulative R&D investment of the Group (the Company and its subsidiaries/units) in the Vaccine was in the amount of approximately RMB14.06 million (unaudited, including licensing fee) at this stage.

## **III. Risk Warning**

1. According to the current approval requirements for vaccine products in the PRC, vaccine products under development need to complete major procedures such as preclinical research, clinical trial approval, clinical phase I, phase II and/or phase III trials, marketing approval, and production facility certification/verification (if applicable) before they can be marketed. Therefore, it is expected that the Vaccine cannot be marketed in the PRC in the short term due to the routine clinical trial and registration process of prophylactic vaccines.

2. As at the date of this announcement, there is still no mRNA-based prophylactic vaccine has yet been approved for launch in the world. The Vaccine has obtained the clinical trial approval by NMPA, and there are still uncertainties whether it will eventually enter clinical trial and the time to start the clinical trial.

3. Based on our experience in vaccine development, there are certain risks in clinical

trial research. If the Vaccine enters the stage of clinical trial, the progress and results of the clinical trial will be affected by (including but not limited to) the clinical trial design, the recruitment of subjects, and the development of the epidemic, and may be terminated due to safety and/or efficacy of the clinical trial, all of which involve uncertainties.

4. Even if the Vaccine is approved to be marketed overseas, there are uncertainties as to whether the Vaccine can obtain the marketing approval from relevant drug regulatory authorities in the Region and the time required to obtain the marketing approval.

5. After the Vaccine is marketed, its sales will also be affected by (including but not limited to) the development of the epidemic, market environment, sales channels and other factors. There are uncertainties as to the sales of the Vaccine in the Region. Meanwhile, according to the Development and License Agreement (i.e. the license agreement) entered into between Fosun Pharmaceutical Industrial and BioNTech on 13 March 2020 (Eastern Time), BioNTech will be supplying the Vaccine and its production and/or supply chain capabilities will also affect future sales of the Vaccine in the Region.

6. The Vaccine is a prophylactic vaccine. According to the vaccination practice of this type of vaccines, its efficacy may vary among individuals, and a small number of vaccine recipients may experience adverse reactions.

Investors should be aware of the investment risks.

Announcement is hereby given.

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

16 July 2020