上海復旦張江生物醫藥股份有限公司

Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd.*

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

(Stock code:1349)

INDICATIVE ANNOUNCEMENT
OBETICHOLIC ACID TABLETS
FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS
RECEIVED THE ACCEPTANCE NOTICE
FOR THE ABBREVIATED NEW DRUG APPLICATION

This announcement is made by Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd.* (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The board of directors (the "**Board**") of the Company is pleased to announce that, Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd* (泰州復旦張江藥業有限公司) ("**Taizhou Fudan-Zhangjiang**"), a subsidiary of the Company, has received the Acceptance Notice (《受理通知書》) issued by the National Medical Products Administration of the PRC (the "**NMPA**"). The Abbreviated New Drug Application ("ANDA") for Obeticholic Acid Tablets (Strength: 5 mg and 10 mg) (the "**Drug**") for the treatment of primary biliary cholangitis (the "**PBC**") has been accepted. Relevant information is as follows:

ABOUT THE DRUG

Drug name:	Obeticholic Acid Tablets
Strength:	5 mg, 10 mg
Registration type:	Chemical drug, class 3 generic drug
Application matter:	Registration of Domestic Drug Marketing Authorization
Acceptance No.	CYHS2403677, CYHS2403676
Applicant:	Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd*

Review conclusion:	Accepted upon review according to the requirements of Article 32 of the Administrative License Law of the People's Republic of China.

The Drug is an agonist for the farnesoid X receptor (the "**FXR**"). The FXR is a nuclear receptor highly expressed in the liver and intestine which is a key regulator of bile acid metabolism. The Drug is a Category 3 Generic Chemical Drug, and its first target indication is for the treatment of PBC.

Such drug has a large market in China which is a country with high incidence of hepatobiliary disease. The Group has engaged a third-party research institution to break through the patent restrictions on the original drug and was granted the patent in China. On 15 March 2021, the National Health Commission, in conjunction with the Ministry of Science and Technology, the Ministry of Industry and Information Technology, the State Medical Insurance Bureau, the National Medical Products Administration and the State Intellectual Property Office, organized experts to select and demonstrate the drugs that are not yet applying for registration and lack of clinical supply (insufficient competition) for the domestic patent due, and formulated the second batch of encouraged generic drugs catalogue, which clearly defined in the catalogue 17 drugs and formulations encouraged to be imitated, including obeticholic acid.

RESEARCH AND DEVELOPMENT INFORMATION AND PROGRESS OF THE DRUG

The Drug obtained the acceptance notice for the investigational new drug application in April 2021 and officially launched the confirmatory clinical study in August 2021 which aims to evaluate its efficacy and safety in Chinese patients with PBC. The clinical study of the Drug had been completed, and recently the Drug has obtained the acceptance letter for the drug marketing authorization application.

If the Drug can be approved for marketing in the future, it will further enrich the Company's product line and enhance the overall competitiveness. According to the requirements of relevant national laws and regulations on drug registration, after the Drug has been accepted for registration application by NMPA, it still need to go through technical review, on-site inspection, administrative approval and other procedures. The time and result of obtaining the drug registration approval document are uncertain. The acceptance of the Drug registration application will not have a significant impact on the Company's near term performance. The Company will fulfill its information disclosure obligations in a timely manner for subsequent progress in strict accordance with relevant regulations.

By order of the Board
Zhao Da Jun
Chairman

As at the date on the publication of this announcement, the Board comprises:

Mr. Zhao Da Jun (Executive Director)
Ms. Xue Yan (Executive Director)
Mr. Shen Bo (Non-executive Director)
Ms. Yu Xiao Yang (Non-executive Director)
Mr. Wang Hong Guang (Independent Non-executive Director)
Mr. Lam Siu Wing (Independent Non-executive Director)
Mr. Xu Pei Long (Independent Non-executive Director)

Shanghai, the PRC

31 October 2024
** For identification purpose only*