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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
THE ABBREVIATED NEW DRUG APPLICATION FOR OBETICHOLIC ACID TABLETS FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS WAS NOT APPROVED

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

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 Notification of Non-Approval of Drug Marketing Application (《藥物上市申請不予批准通知書》) 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 not been approved. 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.	CYHS2403676, CYHS2403677
Applicant:	Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd*

THE RESEARCH AND DEVELOPMENT PROGRESS AND MARKET STATUS OF THE DRUG

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 made breakthroughs in the patent restrictions on the original drug and was granted corresponding patent authorization in mainland China.

The Group has completed the bioequivalence study of the Drug in July 2020, obtained the clinical trial approval notice in July 2021, and completed the first patient enrollment for the confirmatory clinical trial in December 2021. The Group submitted the Abbreviated New Drug Application for the Drug to the NMPA in October 2024, which was accepted for review. The on-site verification of the marketing application registration was completed in June 2025.

The reason for not approving the Drug is: The Drug is a generic drug that has been conditionally approved for marketing abroad but unlisted domestic. The original reference preparations of the Drug have not been routinely approved overseas, and given the lack of proven benefits and the serious risks identified in the study conclusions of the original preparations after they have been marketed, it is not possible to prove that the benefits of the use of Obeticholic Acid in the approved indications overseas would outweigh the risks which is believed that the existing data cannot fully support the approval of the Drug in accordance with the technical requirements for routine approval of Class 3 generic drugs.

IMPACT ON THE COMPANY AND RISK DISCLOSURE

As at the date of this announcement, the cumulative R&D investment in the Drug amounted to approximately RMB125 million (unaudited). In accordance with the relevant accounting standards and the accounting policies of the Company, all such R&D investment have been fully recognized in the profit and loss of the corresponding accounting period when they occur. The non-approval of the Abbreviated New Drug Application of the Drug is not estimated to have a material adverse impact on the financial performance of the Company.

The Group will continue to increase research and development investments and accelerate the advancement of research and development projects. While ensuring that existing products sustain their contributions to the Group's revenue, we will expedite the commercialisation of new products in our core areas of competitive advantage, so as to enhance our core competitiveness and sustainability. **Investors are advised to make cautious decisions and pay careful attention to investment risks.**

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

13 October 2025
* *For identification purpose only*