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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)

VOLUNTARY ANNOUNCEMENT
AMINOLEVULINIC ACID HYDROCHLORIDE GRANULES FOR INTRAOPERATIVE VISUALISATION OF BLADDER CANCER RECEIVED THE ACCEPTANCE NOTICE FOR THE ABBREVIATED NEW DRUG APPLICATION

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

The board of directors (the "**Board**") of the Company is pleased to announce that, 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 aminolevulinic acid hydrochloride granules (the "**Drug**") developed by the company for intraoperative visualization of non-muscular invasive bladder cancer (the "**Study**") has been accepted. Relevant information is as follows:

ABOUT THE DRUG

Drug name:	Aminolevulinic Acid Hydrochloride Granules
Strength:	1.5g/sachet
Registration type:	Chemical drug, class 3 generic drug
Application matter:	Registration of Domestic Drug Marketing Authorization
Acceptance No.	CYHS2602848
Applicant:	Shanghai Fudan-Zhangjiang Bio-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.

Bladder cancer is a kind of malignant tumor with high recurrence rates. According to whether the tumor has penetrated into the bladder muscle, it can be divided into non-muscular invasive bladder cancer (the "**NMIBC**") and muscular invasive bladder cancer (MIBC). According to public information, NMIBC accounts for about 75% of bladder cancers. Transurethral resection of bladder tumor (the "**TURBT**") is currently the preferred surgical treatment for NMIBC, with the goal of completely removing the tumor. In clinical practice, incomplete tumor resection during TURBT is one of the major causes of recurrence of NMIBC. Therefore, the Company intends to develop this intraoperative fluorescence-guided technology to improve the detection rate of NMIBC during TURBT, so as to help surgeons remove tumor completely, thus reducing recurrence in patients.

RESEARCH AND DEVELOPMENT INFORMATION AND PROGRESS OF THE DRUG

The Company has received the approval for the clinical trial application of the Drug in February 2024 and initiated the phase III confirmatory clinical trial in March 2025. The Study aims to evaluate its effectiveness and safety of aminolevulinic acid hydrochloride granules for visualization of non-muscular invasive bladder cancer during transurethral resection of bladder tumor. The clinical trial 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. Zhong Tao (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)
Ms. Qu Ya Nan (Employee Director)

Shanghai, the PRC

19 November 2026
** For identification purpose only*