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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 AMINOLEVULINIC ACID HYDROCHLORIDE GRANULES FOR INTRAOPERATIVE VISUALISATION OF BLADDER CANCER RECEIVED THE ACCEPTANCE NOTICE FOR THE 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 application for confirmatory clinical trial of aminolevulinic acid hydrochloride granules (the “**Drug**”) for visualization of non-muscular invasive bladder cancer during transurethral resection of bladder tumor has been accepted. Relevant information is as follows:

ABOUT THE DRUG

Drug name:	Aminolevulinic acid hydrochloride granules
Registration type:	Chemical drug, class 3 generic drug
Application matter:	Registration of Clinical Trial of Domestic Production of Pharmaceutical Product
Acceptance No.	CYHL2300154
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 (TURBT) is currently the preferred surgical treatment for NMIBC so as to completely remove the tumor. In clinical treatment, incomplete tumor resection in TURBT surgery is one of the important reasons for the recurrence of NMIBC. Therefore, The Company intends to develop this intraoperative fluorescence-guided technology to improve the detection rate of NMIBC during TURBT, which supports doctors to conduct a complete tumor resection so as to reduce the risk of recurrence.

The application for the Drug submitted to the NMPA by the Company was the confirmatory clinical trial for visualization of non-muscular invasive bladder cancer during transurethral resection of bladder tumor.

Due to the high-tech, high-risk and high-value-added characteristics of pharmaceutical products, and the long cycle and numerous stages in the process, there are uncertainties in drug pre-clinical research, clinical trial and commercialization. These many stages make it susceptible to uncertainties and therefore, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively facilitate the above research and development project and 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

18 December 2023

** For identification purpose only*