

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



## 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 GRANULES FOR INTRAOPERATIVE VISUALISATION OF BREAST CANCER RECEIVED THE ACCEPTANCE NOTICE FOR THE INVESTIGATIONAL 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 investigational new drug (the “**IND**”) application for Phase II clinical trial of aminolevulinic acid granules (the “**Drug**”) for intraoperative visualisation of breast cancer in adult breast conservative surgery has been accepted. Relevant information is as follows:

#### **ABOUT THE DRUG**

Drug name:	Aminolevulinic acid granules
Registration type:	Class 2.4 improved new drug
Application matter:	Registration of Clinical Trial of Domestic Production of Pharmaceutical Product
Acceptance No.	CXHL2301260
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.

Breast cancer is one of the most common malignant tumors in women with the incidence ranking the first in female tumors, which seriously endangers women's physical and mental health. According to IARC data, China ranks first in the world in the number of new breast cancer cases in 2020, with about 420,000 cases. At present, the main diagnosis and treatment methods of breast cancer include surgical treatment, radiotherapy, chemotherapy, targeted therapy and immunotherapy, among which breast-conserving surgery for patients with early breast cancer has been widely recognized. The goal of breast-conserving surgery is to completely remove the tumor while preserving the surrounding healthy tissues as much as possible. However, the current technology is not yet sufficient to doctors to determine in real-time whether the tumor has been completely removed. The Company intends to develop this intraoperative fluorescence-guided technology to visualize the residual tumor and the resection margin, so as to guide the resection range in real time, to help the patients in China and fulfill the unmet medical needs in clinical practice.

The IND application for the Drug submitted to the NMPA by the Company was the Phase II clinical trial application of the effectiveness and safety of fluorescence diagnosis during breast-conserving surgery for early breast cancer.

**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

13 November 2023

*\* For identification purpose only*