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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 POWDER FOR ORAL SOLUTION FOR INTRAOPERATIVE VISUALISATION OF GLIOMA 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, 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 application for confirmatory clinical trial of aminolevulinic acid hydrochloride powder for oral solution (the “**Drug**”) for intraoperative visualisation of glioma (WHO grade III or IV) has been accepted. Relevant information is as follows:

#### ABOUT THE DRUG

Drug name:	Aminolevulinic acid hydrochloride powder for oral solution
Registration type:	Chemical drug, class 3 generic drug
Application matter:	Registration of Clinical Trial of Domestic Production of Pharmaceutical Product
Acceptance No.	CYHL2300157
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.

Glioma is the most common primary intracranial tumor, which is characterized by high incidence, high recurrence rate, high mortality rate and low cure rate. Surgical resection is the stand of care at domestic and abroad, and the survival and prognosis of patients is related to the degree of surgical resection. Therefore, the basic principle of surgery is to remove as much diseased tissue as possible without damaging adjacent normal brain tissue. However, most of the gliomas are invasive growth. The boundary between gliomas and the surrounding normal brain tissue is not clear so that it is difficult to conduct complete surgical resection. The Company intends to develop this intraoperative fluorescence-guided technology to visualize the tumour margin, so as to guide the resection range in real time, to help surgeons improve complete resection rate while reserving healthy tissue. The Company wish this technology could improve the postoperative quality of life of patients and prolong the survival period of patients.

The application for the Drug submitted to the NMPA by Taizhou Fudan-Zhangjiang was the confirmatory clinical trial for photodynamic diagnosis of malignant gliomas.

**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

27 December 2023

*\* For identification purpose only*