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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 ABBREVIATED NEW DRUG APPLICATION

This announcement is made by Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd.* (the "**Company**", together with its subsidiaries, the "**Group**") 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 Abbreviated New Drug Application ("ANDA") for aminolevulinic acid hydrochloride powder for oral solution (the "**Drug**") indicated in adults for intraoperative visualisation of malignant tissue for malignant glioma (CNS WHO grade III to IV) has been accepted. Relevant information is as follows:

ABOUT THE DRUG

Drug name:	Aminolevulinic Acid Hydrochloride Powder For Oral Solution
Strength:	1.5g/vial
Registration type:	Chemical drug, class 3 generic drug
Application matter:	Registration of Domestic Drug Marketing Authorization
Acceptance No.	CYHS2600302
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 refers to tumors originating from glial cells and is the most common primary intracranial tumor, accounting for approximately 80% of all malignant brain tumors. It is typically characterized by a high disability rate, high recurrence rate, high mortality, and short survival duration. According to publicly available data, the five-year mortality rate glioma in China ranks second only to that of pancreatic cancer and lung cancer among all systemic tumors[1]. Surgical resection is the first-line treatment for glioma, and patient survival prognosis is closely associated with the extent of surgical resection[2]. Therefore, the fundamental principle of surgery is to remove as much of the tumor tissue as possible without damaging adjacent healthy brain tissue. However, high-grade gliomas mostly exhibit infiltrative growth, have ill-defined boundaries with the surrounding normal brain tissue, making conventional surgical procedures relatively difficult to perform.

The Company intends to develop an intraoperative fluorescence-guided technology to indicate the margins of glioma, locate and guide the extent of resection range in real time, and assist surgeons in improving the gross total resection rate of tumors while preserving healthy tissue to the greatest extent possible. This aims to reduce postoperative neurological deficits, enhance patients' postoperative quality of life, and prolong patient survival.

RESEARCH AND DEVELOPMENT INFORMATION AND PROGRESS OF THE DRUG

Taizhou Fudan-Zhangjiang, a subsidiary of the Company, has received the acceptance notice for the confirmatory clinical trial application in December 2023 and officially launched the confirmatory clinical study in June 2024 which aims to evaluate its effectiveness and safety of aminolevulinic acid hydrochloride powder for oral solution in fluorescence-guided tumour resection surgery for adult patients with malignant high-grade glioma (CNS WHO grade III to IV). The clinical study 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

[1] "Diagnosis and Treatment Guidelines for Glioma (2022 Edition)" issued by the National Health Commission

[2] "Guidelines for Integrated Treatment of Glioma (2024 Edition)" issued by the Chinese Anti-Cancer Association (CACA)

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)
Ms. Qu Ya Nan (Employee Director)

Shanghai, the PRC

29 January 2026
** For identification purpose only*