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
FIRST PATIENT ENROLLED IN PHASE III CLINICAL TRIAL OF FDA018 ANTIBODY DRUG CONJUGATE FOR INJECTION FOR THE TREATMENT OF TRIPLE NEGATIVE BREAST CANCER

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

The first patient in phase III clinical trial of FDA018 antibody drug conjugate for injection (Trop2-SN38 ADC, the "**Drug**") for the treatment of triple negative breast cancer ("**TNBC**")of the Company (the "**Study**") has recently been successfully enrolled in the Study.

ABOUT THE DRUG

The Drug is composed of monoclonal antibodies against human trophoblast cell surface glycoprotein antigen ("**Trop-2**") target coupled with SN38. Trop-2 is expressed at different levels, and its expression level is significantly increased in various carcinomas, such as breast cancer, lung cancer, and gastric cancer. The Drug can bind to high Trop-2-expressed tumor cells and endocytosis, releasing small molecule cytotoxic drugs (topoisomerase I inhibitors) in lysosomes by protease cleavage to kill the tumor cells. The Drug is intended to be developed for the treatment of advanced solid tumors including but not limited to breast cancer, urothelial cancer, non-small-cell lung cancer, cervix cancer and gastric cancer, etc.

RESEARCH AND DEVELOPMENT INFORMATION AND PROGRESS OF THE DRUG

In May 2024, the results of the phase I clinical study of the Drug were published on the website of the American Society of Clinical Oncology (ASCO). Based on clinical data from monotherapy with the Drug, as of 8 October 2023, a total of 62 patients have received at least one dose of the Drug which has been shown to be well tolerated with a manageable safety profile, with maximum tolerated dose (MTD) not yet achieved as of the 12.0 mg/kg dose. Of the 29 TNBC patients treated at the 10.0 mg/kg dose with evaluable efficacy, the overall response rate (ORR) and disease control rate (DCR) were 37.9% and 79.3%, respectively, demonstrating encouraging preliminary antitumor activity.

The Study of the Drug a randomised, controlled clinical trial evaluating its efficacy, safety, pharmacokinetics and immunogenicity in patients with TNBC. As at the date on the publication of this announcement, the first patient has been successfully enrolled in the Study.

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

26 August 2024
** For identification purpose only*