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友芝友生物製藥

WUHAN YZY BIOPHARMA CO., LTD.
武漢友芝友生物製藥股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock code: 2496)

VOLUNTARY ANNOUNCEMENT
PHASE Ib INTERIM STUDY DATA OF M701 FOR THE TREATMENT OF MALIGNANT PLEURAL EFFUSION PRESENTED AT THE ESMO CONGRESS 2024

This announcement is made by Wuhan YZY Biopharma Co., Ltd. (the "**Company**") on a voluntary basis to inform the shareholders and potential investors of the Company of the latest business updates of the Company.

The board of directors of the Company (the "**Board**") is pleased to announce that, the data from an interim analysis of Phase Ib clinical study of M701, a bispecific antibody ("**BsAb**") drug candidate dually targeting epithelial cell adhesion molecule ("**EpCAM**") and cluster of differentiation 3 ("**CD3**") independently developed by the Company, for the treatment of malignant pleural effusion ("**MPE**") caused by advanced non-small cell lung cancer in China (the "**Study**") were presented in a poster session at the ESMO (European Society for Medical Oncology) Congress 2024 (Poster No.: 1371P), and will be available on the Company's website (https://www.yzybio.com) accordingly.

The Study is a multi-center, open-label Phase Ib clinical trial (Trial number: M70103) for MPE caused by advanced non-small cell lung cancer. In the Study, patients with advanced non-small cell lung cancer who had failed at least first-line therapy and had symptomatic pleural effusion were enrolled. While maintaining a systematic therapy, they received pleural drainage and intrapleural infusion of M701 at a dose and frequency of 25μg of M701 on day 1 and 50-400μg of M701 on days 4, 7, and 10, respectively (for the 6-dose cohort in the expansion phase, two more doses were administered on days 13 and 16), and the phase II study was conducted after the optimal dose was determined. The primary endpoint of the Study is the safety and tolerability of M701 for intrapleural infusion, and determination of the recommended phase II dose ("**RP2D**"), while the secondary endpoints include pleural effusion efficacy data and immunogenicity.

Safety results: As of April 19, 2024, 24 subjects were enrolled in the Study, including 11 subjects in the dose-escalation phase and 13 subjects in the dose-expansion phase. No DLT (dose limiting toxicity) events occurred during the dose-escalation phase. Finally, the RP2D of 400μg (maintenance dose) for 4 times of administration was determined for the phase II study. During the study period, there were no SAEs (serious adverse events) related to the study drug, and there was only one case of grade 3 TRAEs (treatment-related adverse events), which was neutropenia. M701 has good safety profile for intrapleural infusion.

Efficacy results: In the Phase Ib, M701 showed good pleural effusion control. Among the 13 subjects in the expansion phase, the objective response rate of pleural effusion and the pleurodesis rate at week 4 were both 61.5%. At week 8, the objective response rate of pleural effusion could still reach 53.8%, and the pleurodesis rate could maintain at 61.5%. At the end of the Phase Ib study, the median puncture-free survival (mPuFS) was 237 days. The detection results of tumor cells in the pleural effusion also showed that after 3 intrapleural infusions of M701, the EpCAM-positive tumor cells decreased significantly compared with the baseline.

Based on the above favorable safety and efficacy results, the Company is actively promoting the phase II clinical study of MPE, which is a randomized controlled study to compare the efficacy and safety of intrapleural infusion of M701 or cisplatin in controlling MPE in patients with non-small cell lung cancer.

ABOUT MALIGNANT PLEURAL EFFUSION

MPE is a complication commonly found in patients with advanced lung cancer, breast cancer and other cancers. It is caused by abnormal endothelial cells and increased exudates due to invasion of tissues by tumor cells and the release of negative factors, as well as accumulation of lymphatic fluid due to blockage of lymphatic vessels by tumor cells. MPE not only causes symptoms that significantly impact patients' quality of life, such as chest tightness, dyspnea, chest pain, nausea and vomiting, but also affects physicians' evaluation of the efficacy of current systemic therapies. There is still a lack of clinical drugs for MPE in China. In European and American countries, intrapleural administration of talcum powder is recommended for MPE to promote pleural adhesion, thereby inhibiting the production of exudates. However, this approach has severe side effects. Safer and more effective innovative drugs are urgently needed for patients.

ABOUT M701

M701, a BsAb, is an innovative Category I biological drug that can target both EpCAM (as the target on tumor cells) and CD3 (as the immune T cell activation target). Its main mechanism of action involves binding to both tumor cells and immune T cells through these targets, thereby activating T cells to kill tumor cells. Therefore, intraperitoneal/intrapleural infusion of M701 can activate immune cells to selectively eliminate and suppress tumor cells in the abdominal/pleural cavity. M701 is undergoing various stages of clinical trials for malignant ascites (MA) and MPE in China, including a pivotal Phase III clinical trial for MA caused by epithelial solid tumor and a Phase II clinical trial for MPE caused by non-small cell lung cancer.

ABOUT THE COMPANY

We are a biotechnology company dedicated to developing BsAb-based therapies. We have prospectively forayed into a number of therapeutic areas with vast potential, including but not limited to tumor complications, oncology, ophthalmology and autoimmune diseases. In particular, we have been focusing on developing the T cell-engaging BsAb (including M701), and the tumor microenvironment (TME)-targeted BsAbs, including Y101D and Y332. We have two core products: M701 and Y101D. M701 is a recombinant BsAb that targets cancer cells expressing human EpCAM and T cells expressing human CD3. We are developing M701 primarily for the treatment for MA and MPE, which are severe complications of cancer characterized by the accumulation of fluids in the abdominal or chest cavity of cancer patients. We are developing Y101D, a recombinant anti-PD-L1 and anti-TGF-β humanized BsAb, for the treatment of solid tumors.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that M701 will ultimately be successfully developed and marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Wuhan YZY Biopharma Co., Ltd.
Dr. Zhou Pengfei
Chairman of the Board, Executive Director and Chief Executive Officer

Wuhan, PRC, September 23, 2024

As of the date of this announcement, the Board comprises Dr. Zhou Pengfei as executive director, Dr. Yuan Qian, Dr. Zhou Hongfeng, Mr. Pang Zhenhai, Dr. Hui Xiwu, Ms. Liang Qian, Dr. Guo Hongwei and Mr. Xie Shouwu as non-executive directors, and Dr. Cheng Bin, Ms. Fu Lili, Dr. Deng Yuezhen and Dr. Chen Bin as independent non-executive directors.