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 II STUDY INTERIM DATA OF M701 FOR MALIGNANT PLEURAL EFFUSION PRESENTED AT THE ESMO CONGRESS 2025

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 study interim data of Phase II 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 ("**NSCLC**") in China (the "**Study**") were presented in a poster at the European Society for Medical Oncology ("**ESMO**") Congress 2025 (Poster No.: 1880P), and will be available on the Company's website (**https://www.yzybio.com**) accordingly.

The Study is a randomized controlled, multi-center, open-label Phase II clinical trial (Trial number: M70103) for MPE caused by NSCLC. In the Study, subjects in the experimental group and the control group were enrolled at a ratio of 1:1. Subjects in the experimental group received pleural drainage and then intrapleural infusion of M701. Subjects in the control group received pleural drainages and then intrapleural infusion of Cisplatin. The primary endpoint of the Study is puncture-free survival ("**PuFS**"), which is defined as the time from the end of treatment to the intolerance of MPE or death, which is a composed time to event endpoint and can directly reflects the duration of local intervention in the management of MPE. The secondary endpoints of the Study include MPE objective response rate ("**ORR**"), Time to next puncture (TTNP), symptoms and signs related to MPE, pharmacodynamic and immunogenicity.

As of March 7, 2025, 54 eligible advanced NSCLC patients with symptomatic MPE who had failed in at least 1 line of systemic treatment were enrolled. Enrolled subjects were randomly assigned in the Study at a ratio of 1:1, with 26 subjects in experimental group and 28 subjects in control group. The median age of the experimental group was 66.5 years old and was 61.5 years old of the control group. In the experimental group and control group, the proportion of females was 57.7% and 50.0%, respectively; the proportion of patients with an Eastern Cooperative Oncology Group ("**ECOG**") score of 0–1 was 92.3% and 96.4%, respectively; the proportion of patients with moderate or greater pleural effusion volume (≥500mL) at baseline was 65.4% and 67.9%, respectively; the proportion of patients who were previously treated with thoracentesis was 65.4% and 71.4%, respectively; the proportion of patients with positive driven gene mutations was 76.9% and 78.6%, respectively; the proportion of patients who were previously treated with IP chemotherapy was 42.3% and 35.7%, respectively. With the exception of the older age observed in the experimental group, the baseline profiles of the two groups of patients were relatively balanced.

Efficacy results: The PuFS of the experimental group was longer than that of the control group (median PuFS 130 days versus 85 days, HR (Hazard Ratio)=0.80, p=0.542). The patient with driven gene negative (median PuFS not reached versus 44.5 days, HR (Hazard Ratio)$<$0.01, p$<$0.001) or patients who had a history of IP chemotherapy (median PuFS 253 days versus 72 days, HR (Hazard Ratio)=0.31, p=0.076) got significant benefit in the experimental group. In above population, the MPE ORR of the experimental group and the control group were 72.7% vs 41.7% respectively. At 98 day post randomization, only subjects in the experimental group showed persistent improvement in dyspnea. Flow cytometry analysis revealed that EpCAM+ CD45- tumor cells in pleural effusions were significantly decreased after M701 infusions, but not in the control arm with Cisplatin infusions.

Safety results: Treatment-related adverse events were 3.7% for M701 and 10% for cisplatin arm, only 1 SAE (Grade 2, fever) related to M701.

Conclusion: M701 IP infusion demonstrated remarkable efficacy in managing MPE compared with cisplatin, and was well tolerated, supporting further clinical development, especially in NSCLC patients with no driven gene mutation or patients who received IP chemotherapy previously. This Phase II trial is ongoing and has demonstrated promising potential in preventing the re-accumulation of pleural effusion, particularly in driver gene-negative NSCLC patients, or NSCLC patients who had prior intrapleural chemotherapy. Base on the current favorable outcomes, a pivotal phase III trial is scheduled to be initiated in 2026 to validate its efficacy and safety in a large-scale Chinese population.

ABOUT MALIGNANT PLEURAL EFFUSION

MPE is a significant complication in patients with advanced NSCLC and other epithelial cancers, associated with poor prognosis, reduced quality of life and severe symptoms. In China, local chemotherapy is a common treatment method that can provide non-durable control of MPE.

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 infusion of M701 can activate immune cells to selectively eliminate and suppress tumor cells in the abdominal 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 NSCLC. The Company has granted Chia Tai Tianqing Pharmaceutical Group Co. Ltd. (正大天晴藥業集團股份有限公司) an exclusive, sublicensable license to develop, register, manufacture and commercialize any product that incorporates M701 as well as its stabilizer in the entire field related to the prevention and treatment of human diseases in China. Please refer to the announcement of the Company dated October 8, 2024 for further details.

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 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.

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, October 19, 2025

As of the date of this announcement, the Board comprises Dr. Zhou Pengfei and Mr. Wen Zhicheng as executive directors; Dr. Yuan Qian, Dr. Zhou Hongfeng, Mr. Pang Zhenhai, Dr. Hui Xiwu 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.