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 DATA OF M701 FOR THE TREATMENT OF MALIGNANT ASCITES PRESENTED AT THE 2024 ASCO MEETING

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 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 ascites ("**MA**") caused by advanced epithelial solid tumor in China (the "**Study**") were presented in a poster session at the 2024 American Society of Clinical Oncology ("**ASCO**") annual meeting (Abstract No.: 12060, Poster No.: 189), 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: M70102) for MA caused by advanced epithelial tumor. 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 peritoneal drainage and intraperitoneal infusion of M701 at a dose and frequency of 50 μg of M701 on day 1 and 400 μg of M701 on days 4, 11, and 18, respectively, and were subsequently treated with intraperitoneal infusion of M701 every 2 weeks with no further drainage of ascites. Subjects in the control group received at least 2 peritoneal drainages as needed between day 1 and day 18, with no subsequent drainage of ascites. Subjects in both groups concurrently received a systemic therapy as specified by the investigators. The primary endpoint of the Study is puncture-free survival ("**PuFS**"), which is defined as the time from the end of treatment on day 18 to the next puncture or death, and secondary endpoints of the study include overall survival ("**OS**") and incidence of adverse events.

As of December 15, 2023, 84 patients with advanced epithelial solid tumor with MA were enrolled in the Study. The median age of both the experimental group and the control group was 54 years old, the proportion of males was 33% and 34%, respectively, the proportion of patients with an Eastern Cooperative Oncology Group ("**ECOG**") score of 0-1 was 89% and 88%, respectively, the proportion of patients with gastric cancer in both groups was 49%, the proportion of patients who were previously treated with intraperitoneal medication was 58% and 56%, respectively, and the proportion of patients who were previously treated with peritoneal paracentesis was 63% and 54%, respectively. The baseline profiles of the two groups of patients are relatively balanced.

Efficacy results: The PuFS of the experimental group was significantly longer than that of the control group (median value 54 days versus 24 days, HR=0.39, p=0.001), and subgroup analysis revealed that there was a trend of benefit for subjects with different cancer types, such as gastric cancer, ovarian cancer and colorectal cancer. OS analysis showed a trend toward prolonged survival in subjects treated with M701 (median value 113 days versus 76 days, HR=0.45, p=0.0575), with 6-month survival rates of 35.2% and 15.8% in the experimental group and the control group, respectively. OS analysis of the subgroup showed that the OS of patients with gastric cancer was significantly prolonged in the experimental group (median value 128 days versus 64 days, HR=0.45, p=0.0438).

Safety results: In the experimental group and the control group, the incidence of grade 3 and above treatment emergent adverse events ("**TEAE**") was 52% and 57.5%, and the incidence of serious adverse events ("**SAE**") was 38% and 50%, respectively. Of the subjects treated with M701, only 2 patients reported adverse cytokine release syndrome ("**CRS**") reactions and both were grade 1-2.

Conclusion: Patients with epithelial solid tumor with MA were well tolerated in intraperitoneal infusion of M701 while undergoing systemic therapy and did not demonstrate a higher risk than patients who only underwent peritoneal drainage. Meanwhile, patients treated with M701 showed a prolonged PuFS and OS. These results are promising and strongly support the entry of M701 into pivotal studies as a novel drug for the treatment of MA.

ABOUT MALIGNANT ASCITES

MA is a complication commonly found in patients with advanced cancers. MA often leads to abdominal pain and swelling, dyspnea, nausea, vomiting, malnutrition and anorexia. The causes of MA are independent of the origin of the primary tumor. Tumor-secreted factors lead to tumor neovascularization and increased capillary permeability, resulting in increased plasma inflow into the peritoneal cavity. Tumor cells obstruct lymphatic drainage, leading to decreased fluid efflux from the peritoneal cavity. Patients with MA have poor prognoses, with an average survival time approximately ranging from one to four months after diagnosis. At present, there is a lack of targeted specific drugs and clear treatment guidelines in clinical practice.

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 MA and malignant pleural effusion ("**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 for treating cancer-associated complications, cancer and age-related ophthalmologic 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. Our Core Product, M701, is a recombinant BsAb that targets cancer cells expressing human EpCAM and T cells expressing human CD3. We are primarily developing M701 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, May 24, 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, Dr. Dai Weiguo, Ms. Fu Lili, Dr. Deng Yuezhen and Dr. Chen Bin as independent non-executive directors.