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)

INSIDE INFORMATION
LICENSE AND COLLABORATION AGREEMENT WITH CT TIANQING FOR M701

This announcement is made by the Company pursuant to the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) and Rule 13.09(2) of the Listing Rules.

The Board is pleased to announce that on October 7, 2024 (after trading hours), the Company (as the licensor) and Chia Tai Tianqing Pharmaceutical Group Co. Ltd. (正大天晴藥業集團股份有限公司), a subsidiary of Sino Biopharmaceutical Limited ("**CT Tianqing**", as the licensee), entered into the License and Collaboration Agreement, pursuant to which the Company has granted CT Tianqing an exclusive, sublicensable license to develop, register, manufacture and commercialize the Licensed Product within the Licensed Territory and the Licensed Field.

THE LICENSE AND COLLABORATION AGREEMENT

Grant of License

Pursuant to the License and Collaboration Agreement, the Company has granted CT Tianqing an exclusive, sublicensable license to develop, register, manufacture and commercialize the Licensed Product within the Licensed Territory and the Licensed Field.

Upfront Payment and Development Milestone Payments

CT Tianqing will pay the Company an upfront payment and additional development milestone payment of up to a total of RMB315 million for the Licensed Product based on the progress of research and development.

Sales Milestone Payments and Royalties

CT Tianqing should pay various specified sales milestone payments, based on the achievement of level of annual net sales of the Licensed Product. The maximum sales milestone payments payable by CT Tianqing to the Company is RMB700 million in aggregate.

During the Royalties Term, CT Tianqing should pay the Company a royalty calculated by multiplying the amount of incremental, aggregated net sales of the Licensed Product in the Licensed Territory by the applicable tiered royalty rate ranging from single-digit to low-teen percentages as stipulated in the License and Collaboration Agreement.

INFORMATION ABOUT THE LICENSED PRODUCT

M701, a BsAb, is an innovative Category I biological drug in-house developed by the Company for the treatment of malignant pleural effusion (MPE) and malignant ascites (MA) caused by tumours. It is currently in Phase III clinical trials and is the first CD3/EpCAM bispecific antibody developed in China to enter clinical trials. M701 simultaneously targets the EpCAM marker on tumor cells and the CD3 marker on immune T cells, acting as a bridge between the two. This dual targeting mechanism activates T cells to kill tumor cells. Administering M701 via intraperitoneal or intrapleural perfusion can activate immune cells to target and eliminate or suppress tumor cells in these cavities.

MA and MPE occur in advanced stages of cancer when tumor cells metastasize to the pleura or peritoneum, causing fluid leakage into the chest or abdominal cavity, with inadequate lymphatic drainage. MA and MPE are common complications in middle-to-late-stage cancer patients, with over 600,000 new cases annually in China. More than 10% of cancer patients will develop MA or MPE during their clinical course.

These conditions significantly impact patients' quality of life and survival. Currently, there is a lack of effective standard treatment options. The primary treatment remains fluid drainage combined with local drug perfusion, but the available local therapies are limited, lacking expert consensus guidance and large clinical studies. Patients face poor quality of life and short survival, presenting a significant unmet need. Compared to the current clinical options, M701 offers superior safety and efficacy and is expected to become the standard treatment for pleural and peritoneal effusion.

In February 2024, M701 was approved by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) to conduct a Phase III registration trial for the treatment of MA. Over half of the patients for this trial have been enrolled. Additionally, M701 is undergoing a Phase II clinical trial for MPE caused by non-small cell lung cancer.

In June 2024, the data from an interim analysis of the Phase II clinical trial of M701 for the treatment of MA were presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, showing promising efficacy and safety. Additionally, this trial data was selected for a preferred oral presentation at the 2024 European Society for Medical Oncology (ESMO) Asia Congress (to be released in November 2024). In September 2024, early clinical data on M701 for treating MPE were presented at the ESMO Annual Meeting, demonstrating excellent pleural effusion control and safety.

INFORMATION ABOUT THE PARTIES

CT Tianqing

CT Tianqing is an innovative pharmaceutical group engaged in innovation, research and development, manufacturing and commercialization of high-quality drugs. It is a core enterprise of Sino Biopharmaceutical Limited (01177. HK), a Hong Kong-listed company, committed to provide patients with better health solutions and high-quality affordable medicines. It is well-known for oncology and liver disease drugs in China. CT Tianqing is a national key high-tech enterprise and a backbone enterprise of Lianyungang New Pharmaceutical Industrial Base under the National Torch Plan. It ranks 12th on the 2023 China Pharmaceutical Industry Top 100 Enterprises list and is the Best Industrial Enterprise for Pharmaceutical R&D Products in China in 2024.

Sino Biopharmaceutical Limited, together with its subsidiaries, is a leading, innovative R&D-driven pharmaceutical conglomerate in China. It prides itself on a fully-integrated industrial chain, covering various R&D platforms, intelligent production operations and a formidable sales system. Its products including biopharmaceutical and chemical medicines enjoy an advantageous position in a host of therapeutic areas, such as oncology, liver diseases, respiratory system diseases and surgery/analgesia.

Sino Biopharmaceutical Limited was listed on the Hong Kong Stock Exchange in 2000 and included in 2013 as a constituent stock of MSCI Global Standard Indices – MSCI China Index, Hang Seng Index in 2018, Hang Seng China Enterprises Index in 2019, and Hang Seng Connect Biotech 50 Index and Hang Seng China (Hong Kong-listed) 25 Index in 2020. It has been six years in a row among the "Top 50 Global Pharmaceutical Enterprises" named by the United States authoritative magazine Pharm Exec and was for three consecutive years among the "Asia's Fab 50 Companies" named by Forbes Asia.

The Directors, having made all reasonable enquiries, confirm that, to the best of their knowledge, information and belief, CT Tianqing and its ultimate beneficial owner(s) are third parties independent of the Company and its connected persons (as defined in the Listing Rules).

The Company

The Company is a biotechnology company dedicated to developing BsAb-based therapies. The Company has 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, it has been focusing on developing the T cell-engaging BsAb (including M701), and the tumor microenvironment (TME)-targeted BsAbs, including Y101D and Y332. The Company has two Core Products: M701 and Y101D. M701 is a recombinant BsAb that targets cancer cells expressing human EpCAM and T cells expressing human CD3. The Company is 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. The Company is developing Y101D, a recombinant anti-PD-L1 and anti-TGF-β humanized BsAb, for the treatment of solid tumors.

REASONS FOR AND BENEFITS OF ENTERING INTO THE LICENSE AND COLLABORATION AGREEMENT

The license fee the Company will receive under the License and Collaboration Agreement is revenue in nature and brings several advantages. First, the upfront payment to be received by the Company pursuant to the License and Collaboration Agreement provides immediate revenue to the Company. Furthermore, the Company shares the technology developed through the collaboration. Additionally, by retaining the rights to M701 outside Mainland China and benefiting from cost savings, the Company can continue its development of M701 outside Mainland China while reallocating resources to expand its broader pipelines. This allows the Company to focus on the development of its other drug candidates including Y101D (being one of the Core Products of the Company), Y332 and other pre-clinical assets.

Given that CT Tianqing is primarily engaged in the R&D, manufacture and distribution of pharmaceutical products in the PRC, it holds a strong position in the distribution and sales of innovative products within this market. The Directors believe that the strategic collaboration with CT Tianqing not only facilitates the delivery of M701 to patient communities but also aligns with the Company's mission to accelerate the development of its pipelines and maximize the potential value of M701 in China. This collaboration optimizes the market potential and advance the clinical development of M701.

Therefore, the Directors consider that the terms of the License and Collaboration Agreement are fair and reasonable and the transactions contemplated thereunder are in the interests of the Company and the Shareholders as a whole and in the ordinary and usual course of business of the Group.

IMPLICATIONS UNDER THE LISTING RULES

As the License and Collaboration Agreement and the transactions contemplated thereunder are of a revenue nature in the ordinary and usual course of business of the Group, pursuant to Rule 14.04(1)(g) of the Listing Rules, the License and Collaboration Agreement and the transactions contemplated thereunder do not constitute a notifiable transaction of the Company under Chapter 14 of the Listing Rules.

Cautionary statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that M701 or Y101D 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.

DEFINITIONS

In this announcement, the following expressions have the following meanings, unless the context otherwise requires:

"Board"	the board of directors of the Company
"CMO"	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
"Company"	Wuhan YZY Biopharma Co., Ltd. (武漢友芝友生物製藥股份有限公司), a joint stock company established in the PRC with limited liability on January 13, 2022, or, where the context requires (as the case may be), its predecessor, Wuhan YZY Biopharma Limited Company (武漢友芝友生物製藥有限公司), a limited liability company established in the PRC on July 8, 2010
"Core Product(s)"	the designated "core product(s)" as defined under Chapter 18A of the Listing Rules
"CRO"	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research and development services outsourced on a contractual basis
"CT Tianqing"	Chia Tai Tianqing Pharmaceutical Group Co. Ltd. (正大天晴藥業集團股份有限公司), a limited liability company established in the PRC and a principal subsidiary of Sino Biopharmaceutical Limited
"Directors"	the director(s) of the Company
"Group"	the Company and its subsidiaries
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the United States

"License and Collaboration Agreement"	the license and collaboration agreement dated October 7, 2024 entered into between the Company and CT Tianqing in relation to the Licensed Product
"Licensed Field"	the entire field related to the prevention and treatment of human diseases
"Licensed Product"	any product that incorporates M701 as well as its stabilizer
"Licensed Territory"	Mainland China
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented from time to time
"malignant ascites" or "MA"	the accumulation of fluid in the peritoneal cavity resulting from the growth of primary or metastatic malignant neoplasms in the peritoneum
"malignant pleural effusion" or "MPE"	the collection of fluid in the pleural cavity resulting from malignant disease. Malignant pleural effusions often contain free floating malignant cells
"RMB"	Renminbi, the lawful currency of the PRC
"Royalties Term"	the period commencing upon the first commercial sale of a Licensed Product in the Licensed Territory and ending upon the later of (i) the expiration date of the core molecule patent as stipulated in the License and Collaboration Agreement, and (ii) the tenth anniversary of the first commercial sale of such Licensed Product in the Licensed Territory
"Shareholder(s)"	shareholder(s) of the Company
"Stock Exchange"	The Stock Exchange of Hong Kong Limited

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 7, 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.