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Akesobio

Akeso, Inc.

康方生物科技(開曼)有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9926)

VOLUNTARY ANNOUNCEMENT

PD-1/CTLA-4 BI-SPECIFIC ANTIBODY NOVEL DRUG (AK104) OF THE COMPANY OBTAINED FAST TRACK DESIGNATION FROM FDA FOR TREATING ADVANCED CERVICAL CANCER

This announcement is made by Akeso, Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that, the first-in-class PD-1/CTLA-4 bi-specific antibody novel drug (AK104) independently developed by the Company has obtained fast track designation (FTD) from the Food and Drug Administration of the United States (FDA) for treating advanced cervical cancer. This represents another significant development after receiving the approval from the FDA in April 2020 to initiate a registrational clinical trial of AK104 monotherapy as second-line therapy in patients with recurrent or metastatic cervical cancer.

The fast track program of the FDA is intended to expedite or facilitate the process for reviewing new drugs that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition. A drug candidate with a FTD may be eligible for more frequent communications with the FDA, eligibility for Priority Review (if relevant criteria are met), and rolling review of the new drug application (NDA). The development and launching of the relevant drug will be therefore accelerated.

ABOUT AK104

AK104, a novel, potential next-generation, first-in-class bi-specific PD-1/CTLA-4 immunooncology backbone drug independently developed by the Company, is designed to achieve preferential binding to tumor infiltrating lymphocytes (“**TIL**”) rather than normal peripheral tissue lymphocytes. AK104 simultaneously targets two immune checkpoint molecules: programmed cell death protein 1 (PD-1) and cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), and has demonstrated the clinical efficacy of the combination therapy of PD-1 and CTLA-4 monoclonal antibodies, together with a favorable safety profile that the combination therapy of PD-1 and CTLA-4 monoclonal antibodies has failed to offer. Our AK104 project has been incorporated in the Major New Drug Innovation Program under the 13th Five-year Plan for Major Technology Project (十三五“重大新藥創製”科技重大專項支持專案) issued by National Health Commission and Ministry of Science and Technology in 2017 and has been enlisted in the 2017 Pearl River Talent Program of Guangdong Province — Introduction of Innovation and Entrepreneurship Team Support Program (2017年廣東省“珠江人才計劃”引進創新創業團隊支持專案). It was also jointly rated by China Medical Biotechnology Association and Chinese Medicinal Biotechnology as one of the 2017 Top Ten Medicinal Biotechnology Advancements in China (2017年中國醫藥生物技術十大進展).

INFORMATION ABOUT THE COMPANY

The Company is a biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of innovative antibody drugs that are affordable to patients worldwide. Since the Company’s establishment, the Company has established an comprehensive end-to-end drug development platform (ACE Platform) and system, encompassing fully integrated drug discovery and development functions, including target validation, antibody drug discovery and development, CMC process development, and GMP-compliant commercial scale manufacturing. The Company has also successfully established a bi-specific antibody drug development technology (Tetrabody technology). The Company currently has a pipeline of over 20 innovative investigative drugs for the treatment of major diseases like cancer, autoimmune diseases, inflammation and metabolic diseases, 9 of which have entered clinical stage, including two novel first-in-class bi-specific antibody drugs (PD-1/CTLA-4 and PD-1/VEGF). The Company’s vision is to become a global leading biopharmaceutical company through efficient and break-through research and development in innovating and developing new drugs that are first-in-class and best-in-class therapies.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

- PD-1 programmed cell death protein 1, an immune checkpoint receptor expressed on T-cells, B-cells and macrophages. The normal function of PD-1 is to turn off the T-cell mediated immune response as part of the process that discourages a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of T-cells attaches to certain proteins on the surface of a normal cell or cancer cell, T-cells will turn off its ability to kill the cancer cell
- CTLA-4 cytotoxic T-lymphocyte-associated protein 4, which downregulates T cell immune response to cancer cells

Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that AK104 will ultimately be successfully developed and marketed by the Company. 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
Akeso, Inc.
Dr. XIA Yu
Chairwoman and executive director

Hong Kong, August 12, 2020

As at the date of this announcement, the Board comprises Dr. XIA Yu as chairwoman and executive director, Dr. LI Baiyong, Dr. WANG Zhongmin Maxwell and Mr. XIA Yu (Ph.D.) as executive directors, Mr. LIN Lijun and Dr. ZHOU Yi as non-executive directors, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.