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

NEW DRUG APPLICATION FOR CADONILIMAB (PD-1/CTLA-4 BI-SPECIFIC ANTIBODY) FOR THE TREATMENT OF RELAPSED OR METASTATIC CERVICAL CANCER ACCEPTED BY NMPA

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**") announces that the National Medical Products Administration (the "**NMPA**") of the People's Republic of China ("**China**") has officially accepted the new drug application for the world's first-in-class Cadonilimab (PD-1/CTLA-4 bi-specific antibody, research and development code: AK104) for the treatment of relapsed or metastatic cervical cancer, which has received priority review. Cadonilimab, independently developed and manufactured by the Company, is the first PD-1 based bi-specific antibody drug in the world to submit new drug application. Cadonilimab is the second innovative antibody drug independently developed by the Company to submit the new drug application and the fifth new drug application submitted by the Company in China and in the United States.

The clinical trial data has shown that Cadonilimab has favorable efficacy and safety for the treatment of relapsed or metastatic cervical cancer patients after the failure of platinum-based chemotherapy. Among the target indication population, Cadonilimab has shown better efficacy compared to the published data of PD-1 monoclonal antibody in the market. Relevant clinical data will be published in relevant international conferences and medical journals.

Although PD-1 monoclonal antibody for the treatment of cervical cancer indication has been approved for global market launch, but the clinical study results show that it only achieves an objective response rate of not more than 15% in second-line or more PD-L1 positive patients. The efficacy and safety data of Cadonilimab as monotherapy shown in the phase II pivotal clinical trial are encouraging. Not only does it achieve a higher response rate among PD-L1 positive population, it also shows good effect in PD-L1 negative population, with a significant improvement in the median progression-free survival, offering better treatment for patients with advanced cervical cancer in China. 2030 is the critical year for both initiatives "Global Strategy to Accelerate the Elimination of Cervical Cancer" and "Healthy China 2030". The Company believes that Cadonilimab will be the first self-developed bi-specific antibody drug in China that facilitates the smooth implementation of the global cervical cancer initiative and the health strategy of China as mentioned above.

Cervical cancer has the highest incidence among gynecological malignancies in China, and patients with advanced recurrent metastatic cervical cancer are refractory to routine treatment. This represents one of the biggest challenges faced by gynecologic oncologists with significant clinical needs. The clinical efficacy of immune checkpoint inhibitors as monotherapy is not satisfactory. Despite the potential improvement in efficacy in combination with other treatments, its clinical application is greatly restricted due to severe toxic side effects. The clinical trials of Cadonilimab have demonstrated high efficacy, low susceptibility to toxic side effects as well as safe and controllable results to patients with advanced recurrent metastatic cervical cancer who have failed routine treatment. Cadonilimab has already entered the fast track designation process.

The Company will dedicate its leading advantages in the field of bi-specific antibodies, accelerate the clinical research of Cadonilimab in other indications. The Company is looking forward to the advantages of Cadonilimab in the immuno-oncology therapy to benefit more oncology patients.

INFORMATION ABOUT CADONILIMAB (PD-1/CTLA-4 BI-SPECIFIC ANTIBODY, AK104)

Cadonilimab (AK104) is a novel, potential next-generation, first-in-class bi-specific PD-1/CTLA-4 immuno-oncology backbone drug independently developed by the Company, and its major indications include liver cancer, cervical cancer, lung cancer, gastric cancer, esophageal squamous cell cancer and nasopharyngeal carcinoma. The preliminary research data of cervical cancer, gastric cancer and other tumors shows that, as compared with the combination therapy of PD-1 and CTLA-4, Cadonilimab has much lower toxicity and demonstrated promising safety profile and efficacy. 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 the 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 the 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 new innovative antibody drugs that are affordable to patients worldwide. Since the Company's establishment, the Company has established an end-to-end comprehensive drug development platform (ACE Platform) and system, encompassing fully integrated drug discovery and development functions, including target validation, antibody drug discovery and development, CMC production process development, and GMP compliant scale production. The Company has also successfully developed a bi-specific antibody drug development technology (Tetrabody technology). The Company currently has a pipeline of over 20 innovative drugs for the treatment of major diseases like tumors, autoimmune diseases, inflammation and metabolism diseases, 13 of which have entered clinical stage, including two 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 research and development of high efficacy and breakthrough new drugs that are first-in-class and best-in-class therapies.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

CMC	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
CTLA-4	cytotoxic T-lymphocyte-associated protein 4, which downregulates T cell immune response to cancer cells
GMP	the Good Manufacturing Practice, which comprise guidelines and regulations from time to time issued pursuant to the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) as part of quality assurance
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 cell
PD-L1	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
VEGF	vascular endothelial growth factor, a family of cytokines critical for the growth and development of cancer cells. There are three main VEGF receptors and subtypes of VEGFs, including VEGFR-1, VEGFR-2 and VEGFR-3

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 the Cadonilimab (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, September 24, 2021

As at the date of this announcement, the Board of the Company 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. XIE Ronggang and Dr. ZHOU Yi as non-executive directors, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.