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

EARLY COMPLETION OF PATIENT SCREENING FOR ENROLLMENT IN A PIVOTAL PHASE II CLINICAL TRIAL FOR THE CADONILIMAB (PD-1/CTLA-4 BI-SPECIFIC ANTIBODY) FOR TREATING PATIENTS SUFFERING FROM RELAPSED OR METASTATIC CERVICAL CANCER IN THE PRC

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 Company has completed the patient screening for enrollment in advance in a pivotal Phase II clinical trial for the first-in-class novel drug Cadonilimab (PD-1/CTLA-4 bi-specific antibody; research and development code: AK104), which is a novel immuno-oncology therapy independently developed by the Company for treating patients suffering from relapsed or metastatic cervical cancer after standard therapies. The Company will subsequently communicate with the National Medical Products Administration of the People's Republic of China (the "**PRC**" or "**China**") Center for Drug Evaluation ("**CDE**") based on the results of the primary endpoint analysis for pre-new drug application (Pre-NDA). If the follow-up procedure progresses smoothly, Cadonilimab is expected to become the world's first new PD-1-based bi-specific antibody drug approved for marketing.

In March 2020, the pivotal Phase II clinical trial for the Cadonilimab for treating patients suffering from relapsed or metastatic cervical cancer after standard therapies was initiated in the PRC. In April 2020, the pivotal Phase II clinical trial for the Cadonilimab for treating patients suffering from relapsed or metastatic cervical cancer after standard therapies was approved for initiation by the Food and Drug Administration of the United States ("**FDA**"). At present, the enrollment of this clinical trial is also in progress.

Based on its well-performing clinical data, Cadonilimab for treating patients suffering from relapsed or metastatic cervical cancer after standard therapies has obtained fast track designation (FTD) from FDA in August 2020. In October 2020, CDE approved and included Cadonilimab for treating patients suffering from relapsed or metastatic cervical cancer after standard therapies in the "Breakthrough Therapy Designation".

Currently, registrational clinical trials of Cadonilimab for treating patients suffering from relapsed or metastatic cervical cancer are also launched simultaneously in Australia and New Zealand. Major indications for the application of Cadonilimab also include liver cancer, gastric cancer, lung cancer, esophageal squamous cell carcinoma, and nasopharyngeal cancer.

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

Cadonilimab (AK104), a novel, potential next-generation, first-in-class bi-specific PD-1/CTLA-4 immuno-oncology backbone drug independently developed by the Company, is designed to achieve preferential binding to tumor infiltrating lymphocytes (TIL) rather than normal peripheral tissue lymphocytes. Cadonilimab 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); and 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 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 product 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

VEGF	vascular endothelial growth factor, a family of cytokines critical for the growth and development of cancer cells. There are three main subtypes of VEGF receptors (VEGFR), 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 Cadonilimab 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, December 2, 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. 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.