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

CADONILIMAB (PD-1/CTLA-4 BI-SPECIFIC ANTIBODY) OBTAINED ORPHAN DRUG DESIGNATION FROM FDA OF THE UNITED STATES FOR TREATING 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 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, has obtained orphan drug designation from the Food and Drug Administration of the United States ("**FDA**") for treating cervical cancer (except very early stage IA1). This represents another significant progress after obtaining fast track designation (FTD) from the FDA and the "Breakthrough Therapy Designation" from the National Medical Products Administration (NMPA) of the People's Republic of China (the "**PRC**") in 2020 for treating patients with recurrent or metastatic cervical cancer after standard therapies.

Currently, there are no approved standard treatment for cervical cancer patient who had received a failed platinum-based chemotherapy. The objective response rate (ORR) for later-line treatment is less than 10%, the progression-free survival is short, the chemotherapy dosage tolerance is low, and the incidence of adverse reactions is relatively high. There is an urgent demand for effective drugs to improve patient treatment. The enrollment of patient in registrational Phase II clinical trial of Cadonilimab for treating patients with recurrent or metastatic cervical cancer after standard therapies has been completed in the PRC.

Originated from the Orphan Drug Act of 1983, drug candidates with orphan drug designation have the opportunity to gain seven years of market exclusivity, along with a series of comprehensive benefits provided by the FDA, including tax credits, exemption from biologics license application fees, deduction of or exemption from prescription drug user fees, research and development funding support, protocol assistance, and accelerated regulatory approval.

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

Cadonilimab (AK104) is a novel, potential next-generation, first-in-class bi-specific PD-1/CTLA-4 immunooncology 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 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 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
VEGF	vascular endothelial growth factor, a family of cytokines critical for the growth and development of cancer cells. There are three main subtypes of VEGFs and VEGF receptors, 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 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, February 23, 2021

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.