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) INITIATED PHASE III CLINICAL TRIAL FOR FIRST-LINE TREATMENT OF ADVANCED GASTRIC ADENOCARCINOMA OR GASTROESOPHAGEAL JUNCTION 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 Company has received the approval from the National Medical Products Administration of the People's Republic of China ("**China**") to initiate a phase III pivotal registrational clinical trial for the global first-in-class novel drug Cadonilimab (PD-1/CTLA-4 bi-specific antibody, research and development code: AK104), an immuno-oncology therapy independently developed by the Company, in combination with oxaliplatin and capecitabine ("**XELOX**") versus placebo in combination with XELOX for first-line treatment of advanced gastric adenocarcinoma or gastroesophageal junction cancer (clinical registration number: CTR20211567) and the national researchers' conference has been successfully held.

The clinical trial is a randomized, double-blind, multicenter, phase III clinical trial comparing the efficacy and safety of AK104 in combination with XELOX to placebo in combination with XELOX for first-line treatment of non-surgically resectable locally advanced or metastatic gastric adenocarcinoma or gastroesophageal junction cancer. The clinical trial is led by Beijing Cancer Hospital as the leading research centre, and it plans to recruit approximately 500 patients to evaluate the efficacy and safety of Cadonilimab in combination with chemotherapy, with progression-free survival (PFS) and overall survival (OS) as primary endpoints.

The clinical trial was led by Beijing Cancer Hospital. Based on the current status of gastric cancer treatment, certain issues such as the advantages and characteristics of PD-1/CTLA-4 bi-specific antibody in gastric cancer treatment and the design and execution of the phase III pivotal clinical trial have been discussed among various researchers and representatives from over 60 hospitals including Beijing Cancer Hospital, Fudan University Shanghai Cancer Center and Fujian Provincial Cancer Hospital.

Experts who participated the conference pointed out that gastric cancer is ranked as the fifth most common malignant tumor in the world, with a high incidence in Asia in particular. Currently, there are new drugs for treatment of human epidermal growth factor receptor 2 ("**HER2**") positive gastric cancer, but the HER2 positivity rate in Chinese gastric cancer patients is only 12% to 13%. More efficient treatment for HER2-negative patients is highly needed. Although the first-line immunotherapy for HER2-negative patients with advanced gastric cancer has succeeded, the current treatment results for HER2-positive patients is barely satisfactory.

Participating experts reached a consensus and agreed that Cadonilimab is a humanized bi-specific antibody that targets both PD-1 and CTLA-4 with a higher affinity for tumor-infiltrating lymphocytes in the tumor microenvironment as compared with surrounding tissues. The results of the preliminary clinical trial showed that Cadonilimab had a better safety profile than PD-1 in combination with CTLA-4 and initially showed better efficacy. The Company is excited about the future of this drug. Especially in the exploratory study of Cadonilimab in combination with chemotherapy for first-line treatment of advanced gastric cancer, low drug dose in combination with chemotherapy demonstrated good efficacy and Cadonilimab showed encouraging anti-tumor activity and sustained tumor response at all dose levels. The Company expects that this clinical trial will yield favorable results and achieve better survival rates for patients with advanced gastric cancer.

Cadonilimab has demonstrated a favorable safety and efficacy profile in a prior clinical trial involving nearly 900 patients with multiple oncology indications, including cervical cancer and gastric cancer. This clinical trial is a multicenter, large scale phase III clinical trial for gastric cancer patients, and is the first phase III clinical trial of PD-1/CTLA-4 bi-specific antibody for gastric cancer in the world. This clinical trial is guided by the unmet global clinical needs, and is a direct manifestation of the Company's commitment and confidence in providing innovative solutions to patients. The Company is looking forward to the early completion of the clinical trial with the efforts of expert teams at its centers across China, bringing new hope for the treatment of gastric cancer 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

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 (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 3, 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.