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

ORAL PRESENTATION OF PHASE II CLINICAL DATA OF CADONILIMAB (PD-1/CTLA-4 BI-SPECIFIC ANTIBODY, AK104) FOR THE FIRST-LINE TREATMENT OF R/M CERVICAL CANCER AT 2022 ASCO ANNUAL MEETING

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 results of phase II clinical trial of Cadonilimab (PD-1/CTLA-4 bi-specific antibody, research and development code: AK104), the world's first-in-class novel immuno-oncology drug independently developed by the Company, combined with platinum-based chemotherapy +/- bevacizumab as first-line treatment for recurrent or metastatic cervical cancer (R/M CC) ("**this trial**") were reported in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.

This trial was a multi-center and open-label Phase II clinical trial (NCT number: NCT04868708) R/M CC, primary endpoints are safety and Objective Response Rate (ORR). The trial is designed with three arms which subjects receiving 15mg/kg or 10mg/kg of Cadonilimab plus platinum-based chemotherapy drugs, and 10mg/kg of Cadonilimab plus platinum-based chemotherapy drugs, plus bevacizumab.

The results showed that Cadonilimab in combination with platinum-based chemotherapy +/- bevacizumab was well tolerated, no new safety signals were observed in the study. In terms of efficacy, the combo-therapy showed promising antitumor activity, regardless of combined positive score (CPS) status.

- At dose of 10mg/kg, regardless of CPS status, Cadonilimab combined with platinum-based chemotherapy +/- bevacizumab, the objective response rate (ORR) was 79.3%; in CPS≥1 and CPS<1 population, ORR was 82.4% and 75.0%, respectively. Progression-free survival (PFS) or overall survival (OS) data is not mature by the cut-off date.

- Among all evaluable patients treated with the 10 mg/kg dose, 41.4% of the patients were PD-L1-negative patients (CPS<1).

- The incidence of ≥3 grade TRAE of the trial was 60.0%.

Based on the excellent efficacy and safety results of phase II study, the Company is conducting a phase III study of Cadonilimab plus platinum-based chemotherapy +/- bevacizumab in first-line treatment for R/M cervical cancer (NCT number: NCT04982237). In addition, a phase III study of Cadonilimab plus concurrent chemoradiotherapy (CCRT) for locally advanced cervical cancer (LACC) is also ongoing (NCT number: NCT05235516).

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

Cadonilimab is a novel first-in-class PD-1/CTLA-4 bi-specific immuno-oncology backbone drug which developed by the Company independently, and its major indications include cervical cancer, gastric cancer, liver cancer, lung cancer, liver cancer, renal cancer, esophageal squamous cell cancer, and other malignant tumors. The periodic research data show that, as compared with the combination therapy of PD-1 and CTLA-4, Cadonilimab has much lower toxicity and demonstrates promising safety profile and efficacy. Based on the positive effects of Cadonilimab obtained in the clinical trial of recurrent/metastatic cervical cancer, CDE accepted the new drug application of Cadonilimab for the treatment of recurrent/metastatic cervical cancer in September 2021.

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 30 innovative drugs for the treatment of major diseases like tumors, autoimmune diseases, inflammation and metabolism diseases, 15 of which have entered clinical stage, including two first-in-class bi-specific antibody drugs Cadonilimab (PD-1/CTLA-4) and Ivonescimab (PD-1/VEGF). In August, 2021, the first independently-developed, distinguished PD-1 monoclonal antibody, Penpulimab Anniko®) was granted marketing approval. 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.

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-cells 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 a cancer cell, T-cells will turn off its ability to kill the cell
PD-L1	Programmed death ligand 1
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 (PD1/CTLA-4 bi-specific antibody, 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, June 6, 2022

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, Dr. ZHOU Yi and Mr. XIE Ronggang as non-executive directors, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.