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)

INSIDE INFORMATION ANNOUNCEMENT

開坦尼® (CADONILIMAB INJECTION) OBTAINED NMPA'S MARKETING APPROVAL IN CHINA

This announcement is made by Akeso, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The board of directors of the Company (the "**Board**") is pleased to announce that 開坦尼® (Cadonilimab injection), a first-in-class PD-1/CTLA-4 bi-specific antibody independently developed by the Company, has been granted marketing approval by the National Medical Products Administration (the "**NMPA**") of the People's Republic of China ("**China**") for the treatment of recurrent or metastatic cervical cancer (R/M CC) patients that who has progressed on or after platinum-based chemotherapy. 開坦尼® is globally first approved dual immune checkpoint inhibitor bi-specific antibody, addressing a huge unmet medical need for immunotherapy for advanced cervical cancer in China, and is also pioneering the development of bi-specific antibody in China.

The approval of 開坦尼® by the NMPA is based on a multicenter, open-label, single-arm, phase II pivotal trial in China. **The results presented at the 2022 Society of Gynecologic Oncology (SGO) Annual Meeting showed that:**

- Among 100 evaluable patients with tumour assessment, the overall response rate (ORR) was 33.0% with complete remission (CR) of 12.0%. The 6-month and 12-month duration of remission (DoR) rate were 77.6% and 52.9% respectively. The median progression-free survival (PFS) and median overall survival (OS) were 3.75 months and 17.51 months respectively.

- Among 64 PD-L1 positive (CPS≥1) patients, ORR was 43.8%, median PFS was 6.34 months, median OS not reached.

- Safety profile: Among the total 111 enrolled patients, the incidence rate of Grade≥3 treatment related adverse events (TRAEs) was 27.0%.

China has the second largest population of cervical cancer patients in the world, with 110,000 new cases in 2020. The Company is now conducting a phase III trial of Cadonilimab plus platinum-based chemotherapy +/- bevacizumab in first-line treatment for R/M CC and has completed patient enrollment. In addition, a phase III trial of Cadonilimab plus concurrent chemoradiotherapy (CCRT) for locally advanced cervical cancer (LACC) is also ongoing.

開坦尼® (Cadonilimab injection) is the second product of the Group obtaining marketing approval from the NMPA following the approval of Anniko® (Penpulimab), and is the first immunotherapy drug independently marketed by the Company.

INFORMATION ABOUT 開坦尼® (CADONILIMAB INJECTION)

開坦尼® (Cadonilimab injection) is a novel global first-in-class PD-1/CTLA-4 bi-specific immuno-therapy drug independently developed by the Company, and it is conducting clinical trials in cervical cancer, gastric cancer, liver cancer, lung cancer, renal cancer, esophageal squamous cell cancer, and other malignant tumors. The research data show that, as compared with the combination therapy of PD-1 and CTLA-4, 開坦尼® demonstrates promising safety profile and efficacy. In June 2022, 開坦尼® has been granted marketing approval by the NMPA of China for the treatment of R/M CC patients that who has progressed on or after platinum-based chemotherapy, which becomes the global first-approved PD-1/CTLA-4 bi-specific antibody.

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 開坦尼® (Cadonilimab) and Ivonescimab (PD-1/VEGF). In August 2021, the first independently-developed, distinguished PD-1 monoclonal antibody, Anniko® (Penpulimab) was granted marketing approval. In June 2022, 開坦尼® (Cadonilimab) was granted marketing approval for the treatment of R/M CC patients. 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
CPS	Combined Positive Score
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 Listing Rules: There is no assurance that the 開坦尼® (Cadonilimab) will ultimately be successfully commercialized 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 29, 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.