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**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**

## 開坦尼<sup>®</sup> (CADONILIMAB INJECTION) BEING INCLUDED IN CSCO GUIDELINES FOR CERVICAL CANCER TREATMENT (2022)

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 Guidelines for Cervical Cancer Treatment (2022) of Chinese Society of Clinical Oncology (CSCO) (《中國臨床腫瘤學會(CSCO)宮頸癌診療指南(2022)》) have been officially published and 開坦尼<sup>®</sup> (Cadonilimab injection), a first-in-class PD-1/CTLA-4 bi-specific antibody independently developed by the Company, was included in the guidelines as the top recommended second-line immunotherapy for recurrent or metastatic cervical cancer (R/M CC).

As the globally first approved dual immune checkpoint bi-specific antibody, Cadonilimab is the first approved immuno-oncology drug for advanced cervical cancer treatment in China. It was granted marketing approval by the National Medical Products Administration (NMPA) at the end of June 2022, addressing the unmet market demand for immunotherapy for cervical cancer. Cadonilimab has been included in the Guidelines for Cervical Cancer Treatment as the top recommendation by CSCO only after 4 months since its approval, which would enable the clinical doctors in China to obtain a more extensive and in-depth understanding of the clinical efficacy of Cadonilimab, that will further help Cadonilimab to satisfy the patients'needs more promptly and extensively by improving their survival benefit.

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 registrational/phase III trial of Cadonilimab plus concurrent chemoradiotherapy (CCRT) for locally advanced cervical cancer (LACC) is also ongoing.

# INFORMATION ABOUT 開坦尼<sup>®</sup> (CADONILIMAB INJECTION)

開坦尼<sup>®</sup> (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<sup>®</sup> demonstrates promising safety profile and efficacy. In June 2022, 開坦尼<sup>®</sup> 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<sup>®</sup> (Penpulimab) was granted marketing approval. In June 2022, 開坦尼<sup>®</sup> (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.

### **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-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
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  $<math>\mathbb{R}^{\textcircled{B}}$  (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, October 17, 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.