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

NMPA APPROVED THE SNDA FOR CADONILIMAB (PD-1/CTLA-4) AS FIRST-LINE TREATMENT FOR 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 National Medical Products Administration ("**NMPA**") of China has approved the supplemental New Drug Application ("**sNDA**") for 開坦尼® (cadonilimab, PD-1/CTLA-4) in combination with platinum-based chemotherapy with or without bevacizumab as first-line treatment of persistent, recurrent or metastatic cervical cancer. This approval addresses the critical unmet needs for immune-based therapies for first-line cervical cancer patients in China and represents a significant step forward in the treatment of this disease, and also marks the third approved indication for cadonilimab in all population patients.

The approval of this sNDA is based on the results of COMPASSION-16/AK104-303. The study met primary endpoints of both progression-free survival (PFS) and overall survival (OS). In the intent-to-treat (ITT) population, the cadonilimab combination regimen demonstrated significant improvement in both endpoints of PFS and OS. Subgroup analyses from COMPASSION-16 study indicated that both PD-L1-positive and PD-L1-negative populations, regardless of bevacizumab inclusion, benefited from the treatment.

Cervical cancer remains one of the most prevalent and deadly cancers among women, with a 5-year survival rate of approximately 17.0% for patients in the advanced stages. In 2022, China reported 150,700 new cervical cancer cases, resulting in the second-largest burden of cervical cancer worldwide. With the approval for first-line treatment of cervical cancer, cadonilimab has achieved comprehensive coverage for the treatment of cervical cancer, offering an innovative treatment option for patients across all stages of cervical cancer.

ABOUT COMPASSION-16/AK104-303

AK104-303 is a Phase III clinical trial of cadonilimab, the world's first approved PD-1/CTLA-4 bi-specific antibody, in combination with platinum-based chemotherapy with or without bevacizumab as a first-line treatment for persistent, recurrent or metastatic cervical cancer. AK104-303 is a randomized, double-blind, multi-centered Phase III clinical trial with primary endpoints of PFS and OS. In this study, the cadonilimab combination regimen showed a notable efficacy benefit in patients with tumors that have a negative PD-L1 expression (CPS＜1), comprising 27.9% of the population in the treatment group, compared to 24.2% in the control group. The results of this trial have been selected as Late-Breaking Abstract (LBA) and published at 2024 International Gynecologic Cancer Society Annual Global Meeting (2024 IGCS), and published in the leading international medical journals, *THE LANCET* and *Nature Reviews Clinical Oncology*.

ABOUT 開坦尼® (CADONILIMAB, PD-1/CTLA-4)

開坦尼® is a novel global first-in-class PD-1/CTLA-4 bi-specific immuno-therapy drug independently developed by the Company. In June 2022, 開坦尼® has been granted marketing approval by the NMPA and became the world's first approved PD-1/CTLA-4 bi-specific antibody. In September 2024, NMPA approved the sNDA of 開坦尼® in combination with chemotherapy as first-line treatment of gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. In May 2025, NMPA approved the sNDA of 開坦尼® in combination with chemotherapy with or without bevacizumab as first-line treatment of cervical cancer. Currently, the Company is conducting more than 28 clinical trials of combination therapies that include cadonilimab. These clinical trials cover 20 indications that include gastric cancer, liver cancer, lung cancer and other types of cancer.

By order of the Board
Akeso, Inc.
Dr. XIA Yu
Chairwoman and executive director

Hong Kong, June 4, 2025

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 Dr. ZHAGN Peng as executive directors, Mr. XIE Ronggang as non-executive director, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.