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

AK104-302, A PHASE III TRIAL OF CADONILIMAB IN COMBINATION WITH CHEMOTHERAPY AS FIRST LINE TREATMENT FOR GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (GC/GEJC) REACHED PRIMARY ENDPOINT OF OVERALL SURVIVAL (OS) AT INTERIM ANALYSIS

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 AK104-302, a Phase III clinical trial of 開坦尼® (cadonilimab, PD-1/CTLA-4), a novel global first-in-class PD-1/CTLA-4 bi-specific immuno-therapy drug independently developed by the Company, in combination with XELOX chemotherapy (oxaliplatin and capecitabine) as first line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) reached primary endpoint at interim analysis. The independent data monitoring committee (IDMC) recommended to file a supplemental new drug application (sNDA) of cadonilimab based on the interim analysis results of this trial.

This trial (AK104-302) is a randomized, double-blind, multi-center Phase III clinical trial with primary endpoint of overall survival (OS). Based on the interim analysis of IDMC, cadonilimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvements in the primary endpoint of OS compared to placebo in combination with chemotherapy. The safety profile of cadonilimab in this clinical trial was consistent with that observed in previously reported results of cadonilimab, no additional safety signals were identified. The results of AK104-302 will be presented at an upcoming medical conference.

The interim analysis results of this trial show that the superior results of cadonilimab combination therapies maintained over its results of Phase II clinical trials and demonstrated significant and meaningful overall survival (OS) improvements and benefits to all comers, regardless PD-L1 status:

- Cadonilimab in combination chemotherapy significantly reduce risk of death of all comers, including PD-L1 CPS≥5 group and PD-L1 CPS<5 group.

- Cadonilimab in combination with chemotherapy demonstrated superior efficacy in PD-L1 CPS<5 group as well as PD-L1 negative group.

The Company will constantly conduct this trial efficiently based on the interim analysis results, and review results with the Center for Drug Evaluation (CDE) of the National Medical Product Administration (NMPA) in China to submit a supplemental new drug application (sNDA) of cadonilimab.

ABOUT AK104-302

AK104-302, a Phase III clinical trial of cadonilimab, the global first approved PD-1/CTLA-4 bi-specific antibody, in combination with XELOX chemotherapy (oxaliplatin and capecitabine) as first line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (GC/GEJC). AK104-302 is a randomized, double-blind, multi-center Phase III clinical trial evaluating cadonilimab in combination with XELOX chemotherapy, compared to placebo in combination with XELOX chemotherapy in intent-to-treat (ITT) population. The primary endpoint of AK104-302 is overall survival (OS). In the ITT population of AK104-302, approximately 60% of patients are accounted to PD-L1 CPS<5 group, which is more close to the real-world population distribution.

ABOUT 開坦尼 (CADONOLIMAB, 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 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. Currently, the Company is conducting multiple clinical trials of cadonilimab combination therapies, covering more than 20 indications including cervical cancer, gastric cancer, liver cancer, lung cancer, renal cancer, esophageal squamous cell cancer.

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 開坦尼® (Cadonilimab, PD-1/CTLA-4) will ultimately be successfully 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, November 7, 2023

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, 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.