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## **VOLUNTARY ANNOUNCEMENT**

### **AK104-303, a Phase III Trial of Cadonilimab Reached Progression-Free-Survival (PFS) Primary Endpoint at Interim Analysis for First Line Treatment of 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 AK104-303, a Phase III clinical trial of 開坦尼<sup>®</sup> (cadonilimab, PD-1/CTLA-4), a novel global first-in-class bi-specific antibody, in combination with platinum-based chemotherapy with or without bevacizumab as first line treatment for persistent, recurrent, or metastatic cervical cancer reached primary endpoint of progression-free-survival (PFS) at interim analysis conducted by the independent data monitoring committee (IDMC), and demonstrates significant survival benefits for all comers.

This trial (AK104-303) is a randomized, double-blind, multi-centered Phase III clinical trial with primary endpoints of progression-free-survival (PFS) and overall survival (OS).

- The IDMC evaluated the PFS at the interim analysis, cadonilimab in combination with platinum-based chemotherapy with or without bevacizumab demonstrated statistically significant and clinically meaningful improvements in PFS (for all comers, including patients with PD-L1 CPS $\geq$ 1 and patients with PD-L1 CPS $<$ 1), compared to placebo in combination with platinum-based chemotherapy with or without bevacizumab.
- No formal statistical analysis was conducted for the other primary endpoint OS because the pre-specified number of OS events has not been reached, while the trend of OS improvement was observed. The trial will continue as planned to confirm OS benefit.

- The safety profile of cadonilimab in this clinical trial was consistent with that observed in previously reported results of cadonilimab, no new safety signals were identified.

### **ABOUT AK104-303**

AK104-303, a Phase III clinical trial of cadonilimab, the global first approved PD-1/CTLA-4 bi-specific antibody, in combination with platinum-based chemotherapy with or without bevacizumab as 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 endpoint of The primary endpoints of AK104-303 are of progression-free-survival (PFS) and overall survival (OS). In AK104-303, the ratio of intent-to-treat (ITT) population with PD-L1 CPS<1 is 26%.

### **ABOUT 開坦尼 (CADONILIMAB, PD-1/CTLA-4)**

開坦尼<sup>®</sup> 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<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. 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, and other malignant tumors.

**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<sup>®</sup> (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 23, 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.*