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**Akesobio**

**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 ACCEPTED THE SUPPLEMENTAL NEW DRUG APPLICATION FOR 開坦尼<sup>®</sup> (CADONILIMAB, PD-1/CTLA-4) IN COMBINATION WITH CHEMOTHERAPY AS FIRST-LINE TREATMENT FOR GASTRIC 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 just accepted the supplemental New Drug Application (“**sNDA**”) for 開坦尼<sup>®</sup> (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, recurrent or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma.

The supplemental new drug application is based on the results of AK104–302, a randomized, double-blind, multi-center Phase III clinical trial with primary endpoint of overall survival (“**OS**”). Based on the interim analysis of independent data monitoring committee (IDMC), cadonilimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvements in the primary endpoint of OS for all comers (regardless of PD-L1 status), compared to placebo in combination with chemotherapy, and significantly reduced risk of death for all comers. 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.

Gastric cancer is one of the most common malignant tumor globally. According to the latest data published by the International Agency for Research on Cancer (IARC) of World Health Organization (WHO), the incidences of gastric cancer around the world and in China have exceeded 1.09 million and 500 thousand respectively in 2020, and mainly of the gastric cancer patients are diagnosed at advanced stage. The Company believes this sNDA of cadonilimab will benefit more gastric cancer patients (regardless of PD-L1 status) by providing a more efficacious and safe therapy, and will further expand its market potential.

#### **ABOUT 開坦尼<sup>®</sup> (CADONOLIMAB, 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.

**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, January 5, 2024

*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.*