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(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 9926)

VOLUNTARY ANNOUNCEMENT THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION ACCEPTED THE SUPPLEMENTAL NEW DRUG APPLICATION FOR 開坦尼® (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 accepted the supplemental New Drug Application ("sNDA") for 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 platinum-based chemotherapy with or without bevacizumab as first line treatment for persistent, recurrent, or metastatic cervical cancer.

In June 2022, 開坦尼® has been granted marketing approval by NMPA of China as the second/third-line treatment of recurrent or metastatic cervical cancer patients who have progressed on or after platinum-based chemotherapy. This sNDA is based on AK104–303, which demonstrated cadonilimab's superior improvement to all comers (regardless of PD-L1 expression). This sNDA of 開坦尼® will advance into first-line treatment of cervical cancer and benefit all comers of advanced cervical cancer patients.

This is the third indication of 開坦尼[®] submitting new drug application. Earlier in January 2024, NMPA accepted the sNDA of 開坦尼[®] in combination with chemotherapy as first-line treatment of gastric or gastroesophageal junction (G/GEJ) adenocarcinoma, which will bring a more efficacious and safe therapy to all comers (regardless of PD-L1 expression) of gastric cancer patients.

ABOUT AK104-303

AK104–303 is 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 progression-free-survival (PFS) and overall survival (OS).

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 and became the global first approved PD-1/CTLA-4 bi-specific antibody. In January 2024, NMPA accepted the sNDA of 開坦尼[®] in combination with chemotherapy as first-line treatment of gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. Currently, the Company is conducting 20 clinical trials of cadonilimab combination therapies, covering 16 indications including cervical cancer, gastric cancer, liver cancer, lung cancer, renal cancer, esophageal squamous cell cancer.

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

Hong Kong, April 24, 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.