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VOLUNTARY ANNOUNCEMENT

NMPA APPROVED THE SNDA OF 開坦尼® (CADONILIMAB, PD-1/CTLA-4) IN COMBINATION WITH CHEMOTHERAPY AS A 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 has updated the status of the supplemental New Drug Application (“**sNDA**”) 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, to “certificate completed”. The approved indication is cadonilimab in combination with fluoropyrimidine and platinum-based chemotherapy as a first-line treatment of locally advanced, unresectable or metastatic gastric or gastroesophageal junction (“**G/GEJ**”) adenocarcinoma. This is the second indication of 開坦尼® in China. Cadonilimab effectively addresses the efficacy gap of PD-1/L1 monoclonal antibodies in patients with low or negative PD-L1 expression, providing a more comprehensive and effective immunotherapy option for advanced gastric cancer. This advancement benefits all patient populations and presents new opportunities for the global development of gastric cancer immunotherapy, carrying important clinical implications.

The sNDA is based on COMPASSION-15/AK104-302 (NCT05008783), a randomized, double-blind, multi-center Phase III clinical trial with primary endpoint of overall survival (“OS”) and 49.8% of intend-to-treat (“ITT”) population are with PD-L1 CPS<5. The results of the Phase III clinical trial were presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting. As of the interim analysis, the results of this trial showed:

Among ITT population, cadonilimab in combination with chemotherapy significantly improved OS (median overall survival (“mOS”): 15.0 months vs 10.8 months), and significantly decreased risk of death of all comers (OS HR 0.62 (95% CI: 0.50–0.78), P<0.001), compared to placebo in combination with chemotherapy.

OS benefits in different subgroups were consistent with that of ITT population.

- mOS of CPS≥5 population: Not reached vs 10.6 months, HR 0.56 (95% CI: 0.39–0.80), P<0.001
- mOS of CPS<5 population: 14.8 months vs 11.1 months, HR 0.70 (95% CI: 0.51–0.95), P=0.011

The safety profile of cadonilimab is tolerant and manageable, and consistent with that observed in previously reported results of cadonilimab. No additional safety signals were identified.

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® was granted marketing approval by the NMPA for the treatment of recurrent/metastatic cervical cancer patients who have progressed on or after platinum-based chemotherapy, and became the world’s first approved PD-1/CTLA-4 bi-specific antibody. In September 2024, 開坦尼® as a first-line treatment of unresectable locally advanced, recurrent or metastatic G/GEJ adenocarcinoma was approved in China. Currently, the Company is conducting more than 23 clinical trials of cadonilimab combination therapies covering 16 indications including but not limited to cervical cancer, gastric cancer, liver cancer and lung cancer.

By order of the Board

Akeso, Inc.

Dr. XIA Yu

Chairwoman and executive director

Hong Kong, September 30, 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 Dr. ZHANG 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.