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 IVONESCIMAB (PD-1/VEGF) MONOTHERAPY AS FIRST-LINE TREATMENT FOR NSCLC WITH POSITIVE PD-L1 EXPRESSION

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 依達方® (ivonescimab, PD-1/VEGF), a novel global first-in-class PD-1/VEGF bi-specific immuno-therapy drug independently developed by the Company, monotherapy as first-line treatment for locally advanced or metastatic non-small cell lung cancer ("**NSCLC**") patients with positive PD-L1 expression (PD-L1 TPS≥1%).

The sNDA is based on the interim results of AK112–303/HARMONi-2, which demonstrated a significant superiority. Among intent-to-treat (ITT) population, ivonescimab monotherapy achieved statistically significant and clinically meaningful progression-free survival (PFS) benefit versus pembrolizumab monotherapy, and hazard ratio (HR) is significantly better than expected.

Ivonescimab is the globally first and only drug to show superior efficacy compared with pembrolizumab as monotherapy in a Phase III head-to-head setting. Ivonescimab is expected to become the new standard of care of first-line treatment of lung cancer as a chemo-free therapy.

ABOUT AK112–303/HARMONi-2

AK112–303/HARMONi-2 (CTR20222137) is a randomized, double-blind, registrational Phase III clinical trial to evaluate ivonescimab (依達方®) versus pembrolizumab as first-line monotherapy for locally advanced or metastatic NSCLC patients with positive PD-L1 expression (PD-L1 TPS≥1%) with primary endpoint of PFS. 398 participants were enrolled in this trial, and approximate 57.8% of participants were with PD-L1 TPS 1–49% and 42.2% of participants with PD-L1 TPS≥50%, which is in line with real world scenario.

ABOUT 依達方®(IVONESCIMAB, PD-1/VEGF)

依達方®(ivonescimab) is a novel global first-in-class PD-1/VEGF bi-specific immunotherapy drug independently developed by the Company. On May 24, 2024, 依達方®was granted marketing approval by NMPA for the treatment of EGFR mutated locally advanced or metastatic non-squamous NSCLC patients who have progressed after EGFR TKI treatment. Currently, ivonescimab's first indication has been approved in China, and the Company is conducting 5 Phase III trials including 2 global MRCTs and 4 registrational trials versus PD-1. The Company is also conducting multiple clinical trials of ivonescimab covering 16 indications including gastrointestinal cancer, hepatocellular carcinoma and colorectal cancer.

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

Hong Kong, July 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.