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

IVONESCIMAB MEETS OS KEY SECONDARY ENDPOINT IN INTERIM ANALYSIS OF HARMONI-2 STUDY, DEMONSTRATING STATISTICALLY SIGNIFICANT AND CLINICALLY MEANINGFUL BENEFIT VERSUS PEMBROLIZUMAB IN 1L PD-L1-POSITIVE NSCLC

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 its global first-in-class PD-1/VEGF bispecific antibody, ivonescimab, as monotherapy demonstrates significant overall survival (OS) benefit versus pembrolizumab monotherapy in the randomized, double-blind, controlled, multicenter Phase III clinical study (AK112–303/HARMONi-2) for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with positive PD-L1 expression (PD-L1 TPS≥1%). The Independent Data Monitoring Committee (IDMC) declared that the pre-specified interim OS analysis of this study met its key secondary endpoint of OS. The results demonstrated that ivonescimab achieved a statistically significant and clinically meaningful positive improvement versus pembrolizumab. Detailed data will be presented at an upcoming international medical conference and published in a peer-reviewed journal.

The study enrolled a total of 398 patients. The primary endpoint is progression-free survival (PFS), and the key secondary endpoint is OS.

In May 2024, the study met its primary endpoint of PFS, achieving positive results that are statistically significant and clinically meaningful. The median PFS was 11.14 months in the ivonescimab arm versus 5.82 months in the control arm, with a PFS HR of 0.51 (P<0.0001).

The OS results announced this time further demonstrated the ground breaking clinical value of ivonescimab as a next-generation immuno-oncology backbone drug, and create clinically meaningful benefits to cancer patients.

In 2025, this indication was approved for marketing in China. Ivonescimab has broken through the contraindication of anti-VEGF agents in patients with squamous cell carcinoma, offering patients a superior ''chemotherapy-free'' regimen, and has gained trust from clinicians and patients in real-world clinical practice.

About AK112–303/HARMONi-2

AK112–303/HARMONi-2 (CTR20222137, NCT05499390) is a registrational Phase III randomized, double-blind clinical trial evaluating ivonescimab monotherapy versus pembrolizumab monotherapy for the first-line treatment of patients with locally advanced or metastatic NSCLC with positive PD-L1 expression (PD-L1 TPS≥1%) with primary endpoint of PFS and key secondary endpoint of OS. 398 participants were enrolled in this trial. Baseline characteristics were consistent with real-world clinical practice and were well balanced between the treatment and control arms.

ABOUT 依達方® (IVONESCIMAB, PD-1/VEGF)

依達方® (ivonescimab, PD-1/VEGF) 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. On April 25, 2025, the sNDA of ivonescimab as first-line treatment for locally advanced or metastatic NSCLC with PD-L1 positive expression was approved. The above two indications have been included in the latest National Reimbursement Drug List. On August 12, 2026, the sNDA of ivonescimab as first-line treatment of squamous NSCLC was approved. The Company is conducting over 60 Phase II/III clinical trials of ivonescimab covering over 40 indications including lung cancer, biliary tract cancer, head and neck squamous carcinoma, triple negative breast cancer, colorectal cancer, pancreatic cancer, and urothelial cancer. Currently, 17 registrational Phase II/III trials of ivonescimab are ongoing.

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

Hong Kong, September 3rd, 2026

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.