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 APPROVED THE 3RD INDICATION FOR 依達方® (IVONESCIMAB, PD-1/VEGF) AS 1L TREATMENT FOR SQ-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 the supplemental New Drug Application (sNDA) for the global first-in-class bi-specific antibody, 依達方® (ivonescimab, PD-1/VEGF), in combination with chemotherapy for the first-line treatment of advanced squamous non-small cell lung cancer (sq-NSCLC), has received approval from the National Medical Products Administration of the People's Republic of China ("**NMPA**"). This indication marks ivonescimab's third major approval.

The sNDA approval for ivonescimab in combination with chemotherapy for first-line treatment for sq-NSCLC is based on the significant positive results obtained from the randomized, controlled, multi-center Phase III clinical trial (HARMONi-6/AK112–306, NCT05840016, CTR20231272) evaluating ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy as first-line treatment for advanced sq-NSCLC. The positive results from the interim Overall Survival (OS) analysis of this study were presented at the 2026 American Society of Clinical Oncology (ASCO) Plenary Session; and the positive results from the interim Progression-Free Survival (PFS) analysis were presented at the 2025 European Society for Medical Oncology (ESMO) Presidential Symposium:

- In the intent-to-treat (ITT) population, the median Overall Survival (OS) was 27.89 months for the ivonescimab group versus 23.69 months for the control group, with an OS HR=0.66 (95% CI: 0.50–0.87), P=0.0017 (<0.0049).

- In the ITT population, the median Progression-Free Survival (mPFS) was 11.1 months for the ivonescimab group versus 6.9 months for the control group, with a PFS HR=0.60 (95% CI: 0.46–0.78), P<0.0001.

Ivonescimab in combination with chemotherapy demonstrated a favorable overall safety profile, with the overall safety characteristics comparable to those of tislelizumab in combination with chemotherapy.

The results of this clinical study comprehensively demonstrate the transformative clinical value of the ivonescimab combination regimen compared to the PD-1 combination regimen, addressing the clinical gap of the anti-angiogenic drug bevacizumab in the treatment of sq-NSCLC. This result demonstrated the superior efficacy and favorable safety profile of ivonescimab, and with the NMPA approval, brings new hope to more advanced squamous cell NSCLC patients in China.

ABOUT HARMONi-6/AK112–306

HARMONi-6/AK112–306 (NCT05840016/CTR20231272) is a randomized, controlled, multi-center Phase III trial to evaluate ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy as first-line treatment for advanced sq-NSCLC, with primary endpoint of progression-free survival (PFS) by blind IRRC per RECIST v1.1, and key secondary endpoint of overall survival (OS). HARMONi-6 enrolled 532 participants, with balanced baseline characteristics between the treatment group and the control group. 92.3% of the participants had clinical stage IV disease. The squamous carcinoma characteristics of the enrolled participants aligned with clinical practice, with central-type squamous carcinoma accounting for approximately 63% of the total participants, consistent with real-world patient distribution. PD-L1 expression levels also reflected those seen in real-world clinical settings.

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. 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, 16 registrational/Phase III trials of ivonescimab are ongoing, including 6 global MRCTs and 10 trials versus PD-(L)1/anti-angiogenesis treatment. Ivonescimab has demonstrated groundbreaking clinical value across dozens of clinical studies and real-world treatments involving over 70,000 patients.

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

Hong Kong, August 12, 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.