**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 2ND INDICATION FOR IVONESCIMAB (PD-1/VEGF) AS 1L 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 the global first-in-class PD-1/VEGF bi-specific antibody, ivonescimab, has received approval from the National Medical Products Administration ("**NMPA**") for its supplementary New Drug Application (sNDA) for use as a monotherapy for the first-line treatment of PD-L1-positive (TPS≥1%) non-small cell lung cancer (NSCLC) in patients who are negative for epidermal growth factor receptor (EGFR) gene mutations and anaplastic lymphoma kinase (ALK) gene mutations. This indication marks ivonescimab's second major approval.

The sNDA approval is based on the breakthrough results of the AK112–303/HARMONi-2 (CTR20222137, NCT05499390) Phase III study, which is a randomized, double-blind, controlled study that directly compared ivonescimab with pembrolizumab in first-line PD-L1 positive NSCLC.

- In the intent-to-treat (ITT) population, the mPFS of ivonescimab group was 11.14 months, compared to mPFS 5.82 months of pembrolizumab group, achieving a hazard ratio (HR) of 0.51 and reducing the risk of disease progression or death by 49%.

- In the ITT population, an interim analysis of OS conducted at 39% data maturity ($\alpha$=0.0001) indicated a clinically meaningful improvement in OS with ivonescimab compared to pembrolizumab, with a HR of 0.777, reflecting a 22.3% reduction in the risk of death.

Ivonescimab is the first therapy to achieve statistically significant positive results in a Phase III trial compared with pembrolizumab in a head-to-head setting. Ivonescimab represents a new, more effective, and safer ''chemotherapy-free'' option for the first-line treatment of NSCLC.

The Company plans to host a business update call in the morning of April 28, 2025, details of which will be published on the Company's official website and WeChat official account on April 28, 2025 before the call.

**ABOUT AK112–303/HARMONI-2**

AK112–303/HARMONi-2 (CTR20222137, NCT05499390) is a randomized, double-blind, registrational Phase III clinical trial to evaluate ivonescimab versus pembrolizumab as first-line monotherapy for locally advanced or metastatic NSCLC patients with positive PD-L1 expression (PD-L1 TPS≥1%), with 398 participants enrolled.

**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 immuno-therapy 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, 2 indications of ivonescimab have been approved in China. The Company is conducting 12 Phase III trials including 3 global MRCTs and 6 registrational trials versus PD-(L)1. The Company is also conducting multiple clinical trials of ivonescimab covering 18 indications including lung cancer, biliary tract cancer, head and neck squamous carcinoma, triple negative breast cancer, colorectal cancer, pancreatic cancer and hepatocellular carcinoma.

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

Hong Kong, April 27, 2025

*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.*