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

AK112–303 REACHED PRIMARY ENDPOINT OF PFS SUPERIORITY IVONESCIMAB DEMONSTRATED A STATISTICALLY SIGNIFICANT AND CLINICALLY MEANINGFUL SUPERIORITY AS FIRST LINE MONOTHERAPY FOR PD-L1+ NSCLC VERSUS PEMBROLIZUMAB, HAZARD RATIO SIGNIFICANTLY BETTER THAN EXPECTED

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**") announces that the registration phase III clinical trial, AK112–303 (HARMONi-2) of ivonescimab (AK112, PD-1/VEGF), the Company's in-house developed first-in-class bi-specific antibody, versus pembrolizamab as first-line monotherapy for locally advanced or metastatic NSCLC patients with positive PD-L1 expression (PD-L1 TPS≥1%) met primary endpoint of progression-free-survival (PFS) superiority at a prespecified interim analysis conducted by the independent data monitoring committee (IDMC). The PFS benefit was demonstrated across all clinical subgroups, including those with PD-L1 low expression (PD-L1 TPS 1–49%), PD-L1 high expression (PD-L1 TPS≥50%), as well as other high-risk patients.

The results showed

- Among intent-to-treat (ITT) population, ivonescimab monotherapy achieved statistically significant and clinically meaningful PFS benefit versus pembrolizumab, 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 demonstrated significant PFS benefit across patients with PD-L1 TPS 1–49% and PD-L1 TPS≥50%.

- PFS improvement was observed broadly in patients across subgroups, including squamous and non-squamous histologies, or subgroups of patients with/without liver metastases, with/without brain metastases etc.

- 398 participants were enrolled in this trial, including 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.

- The safety profile was good and no additional safety signals were identified.

- The results of AK112–303 (HARMONi-2) will be presented at a global upcoming major medical conference.

In real world scenario, more than 50% of NSCLC patients are with PD-L1 TPS≥1%. The results of this trial strongly prove the superior and broad clinical value of ivonescimab in the first-line treatment of NSCLC.

ABOUT AK112–303 (HARMONI-2)

AK112–303 (HARMONi-2, CTR20222137) is a randomized, double-blind, registration phase III clinical trial to evaluate ivonescimab (依達方®) versus pembrolizamab as first-line monotherapy for locally advanced or metastatic NSCLC patients with positive PD-L1 positive expression (PD-L1 TPS≥1%) with primary endpoint of PFS. 398 participants were enrolled in this trial, including 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 INJECTION, PD-1/VEGF)

依達方® (ivonescimab injection) is a novel global first-in-class PD-1/VEGF bi-specific immuno-therapy drug independently developed by the Company. On May 24th, 2024,依達方® has been granted marketing approval by NMPA of China for the treatment of EGFR mutated locally advanced or metastatic nsq-NSCLC patients who have progressed after EGFR TKI treatment, which becomes the global-approved PD-1/VEGF bi-specific antibody. 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 registration trials versus PD-1. The Company is also conducting multiple clinical trials of ivonescimab covering 16 indications such as gastrointestinal, hepatocellular carcinoma and colorectal cancer.

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

Hong Kong, May 31, 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 Mr. XIA Yu (Ph.D.) as executive directors, Dr. ZHOU Yi and Mr. XIE Ronggang as non-executive directors, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.