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VOLUNTARY ANNOUNCEMENT

HARMONI-6 RESULTS PUBLISHED IN THE LANCET & 2025 ESMO mPFS 11.14m vs 6.9m (HR=0.60, P < 0.0001) FOR IVONESCIMAB PLUS CHEMO VS TISLELIZUMAB PLUS CHEMO IN 1L ADVANCED 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**”) announces that the results of HARMONi-6/AK112–306 trial were presented by Professor Lu Shun, Director of Oncology at Shanghai Chest Hospital, at the 2025 European Society For Medical Oncology (ESMO) Presidential Symposium, and featured in The Lancet simultaneously.

HARMONi-6/AK112–306 (CTR20231272/NCT05840016) is a randomized, double blind, multi center phase III trial to evaluate ivonescimab plus chemo versus tislelizumab plus chemo as first-line treatment for locally advanced or metastatic sq-NSCLC, with primary endpoint of progression-free survival (PFS) by blind IRRC per RECIST v1.1, and key secondary endpoints 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. The results showed:

HARMONi-6 study met its primary endpoint of PFS, demonstrating a decisive and strong positive outcome with both statistically significant and clinically meaningful benefits. Ivonescimab plus chemotherapy substantially extended sq-NSCLC patient survival compared to tislelizumab plus chemotherapy.

Ivonescimab plus chemo demonstrated a significantly prolonged progression-free survival compared to tislelizumab plus chemo, with PFS HR=0.60 ($P < 0.0001$).

- The median PFS (mPFS) of ivonescimab group was 11.14 months, compared to mPFS 6.9 months of the control group.
- HARMONi-6 achieved the meaningful improvement of Δ PFS=4.24 months.

A clinically meaningful benefit was demonstrated across clinical subgroups, including those with either PD-L1 negative or positive expression, as well as high-risk patients.

- PD-L1 TPS < 1%: mPFS 9.9 months vs 5.7 months, PFS HR=0.55 (95%CI: 0.37, 0.82)
- PD-L1 TPS $\geq$ 1%: mPFS 12.6 months vs 8.6 months, PFS HR=0.66 (95%CI: 0.46, 0.95)
- With liver metastases, PFS HR=0.53; without liver metastases, PFS HR=0.64
- With $\geq$ 3 metastases sites, PFS HR=0.46; with < 3 metastases sites, PFS HR=0.64

Ivonescimab demonstrated a favorable safety profile, with no new safety signals identified. The incidence of treatment-related serious adverse events and the incidence of bleeding events of grade 3 or higher were comparable to those of the control group.

The sNDA of this indication has been accepted by CDE. The results of HARMONi-6 demonstrated the breakthrough clinical value of ivonescimab plus chemo compared to PD-1 plus chemo, addressing the clinical gap of the anti-angiogenic drug bevacizumab in the treatment of sq-NSCLC, once again robustly showcasing the superior efficacy and favorable safety profile of ivonescimab and reinforcing its global leadership.

ABOUT HARMONI-6/AK112-306

HARMONi-6/AK112-306 (CTR20231272/NCT05840016) is a randomized, double blind, multi center phase III trial to evaluate ivonescimab plus chemo versus tislelizumab plus chemo as first-line treatment for locally advanced or metastatic sq-NSCLC, with primary endpoint of progression-free survival (PFS) by blind IRRC per RECIST v1.1, and key secondary endpoints 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 patients, 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) 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 Company is conducting over 30 clinical trials of ivonescimab covering 30 indications including lung cancer, biliary tract cancer, head and neck squamous carcinoma, triple negative breast cancer, colorectal cancer, pancreatic cancer, hepatocellular carcinoma. Currently, 14 Phase III trials of ivonescimab are ongoing, including 4 global MRCTs and 7 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 40,000 patients.

By order of the Board

Akeso, Inc.

Dr. XIA Yu

Chairwoman and executive Director

Hong Kong, October 19, 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.