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Akesobio

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

OVER 40 STUDIES PRESENTED AT 2026 ASCO HARMONI-6 RESULTS PUBLISHED IN 2026 ASCO & THE LANCET FOR IVONESCIMAB PLUS CHEMO VS TISLELIZUMAB PLUS CHEMO IN 1L ADVANCED SQUAMOUS-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 development of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that more than 40 clinical studies of its oncology portfolio were presented at the 2026 American Society of Clinical Oncology (“**ASCO**”) Annual Meeting. The datasets featured at 2026 ASCO primarily highlight the Company’s core first-in-class bispecific antibodies — cadonilimab (PD-1/CTLA-4) and ivonescimab (PD-1/VEGF) — along with other novel therapeutic antibodies such as ligufalimab, a next-generation CD47 monoclonal antibody. These presentations include several potentially practice-changing datasets across multiple tumor types, including non-small cell lung cancer (“**NSCLC**”), small-cell lung cancer (SCLC), colorectal cancer (CRC), renal cell carcinoma, melanoma, head and neck cancer, gynecologic malignancies, and biliary tract cancer. The above research results demonstrate the groundbreaking and broad clinical value of the Company’s innovative drugs.

IVONESCIMAB’S HARMONI-6 DATA SELECTED FOR PLENARY SESSION

The results of HARMONi-6/AK112–306 trial were presented by Professor Lu Shun, Director of Oncology at Shanghai Chest Hospital, at the 2026 ASCO Plenary Session, and featured in The Lancet simultaneously. For the first time in 61 years, the Phase III clinical results of first-in-class novel drug from China have been selected as a Late-Breaking Abstract (LBA) for presentation at the ASCO Plenary Session. This achievement signifies the study’s potential to establish a new standard of care and reshape clinical guidelines and practices.

HARMONi-6/AK112-306 (NCT05840016/CTR20231272) 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 squamous-NSCLC (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”).

Positive interim analysis results for OS were also reached and presented at the 2026 ASCO Plenary Session.

In the intention-to-treat (“ITT”) population, the OS hazard ratio (“HR”) between the ivonescimab group and the control group was 0.66 (95% CI: 0.50-0.87), P=0.0017 (<0.0049), representing a 34% reduction in the risk of death in the ivonescimab group.

- The median overall survival (mOS) was 27.89 months in the ivonescimab group versus 23.69 months in the control group.
- The 12-month OS rate was 78.9% in the ivonescimab group versus 72.2% in the control group. The 24-month OS rate was 64.7% in the ivonescimab group versus 48.6% in the control group.

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%: OS HR=0.64
- PD-L1 TPS ≥1%: OS HR=0.68
- PD-L1 TPS 1-49%: OS HR=0.67
- PD-L1 TPS ≥50%: OS HR=0.64
- With ≥3 metastases sites, OS HR=0.47
- With liver metastases, OS HR=0.69

Ivonescimab group demonstrated a favorable safety profile, comparable to those of the control group.

- The incidence of grade ≥3 treatment-related adverse events (TRAEs) in the two groups were 69.2% vs 58.9%
- The incidence of adverse events leading to discontinuation or death in the two groups were comparable

Positive interim analysis results for PFS were presented as a major release at the 2025 European Society for Medical Oncology (ESMO) Plenary Session:

In ITT population, the median PFS (mPFS) was 11.1 months in the ivonescimab group versus 6.9 months in the control group, with a PFS HR of 0.60 (95% CI: 0.46–0.78), $P < 0.0001$.

The supplemental NDA (“sNDA”) of this indication has been accepted by CDE and in its final review, bringing new hope to more patients with sq-NSCLC in China. 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. Akeso, once again showcased the superior efficacy and favorable safety profile of ivonescimab, further solidifying ivonescimab’s leading position as a backbone therapy in global IO 2.0.

ABOUT HARMONI-6/AK112-306

HARMONi-6/AK112-306 (NCT05840016/CTR20231272) 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, PD-1/VEGF) is a novel global first-in-class PD-1/VEGF bispecific immunotherapy drug independently developed by the Company. On May 24, 2024, 依達方[®] was granted marketing approval by the 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. Both indications have been included in the latest National Reimbursement Drug List (the “NRDL”). The Company is conducting over 60 Phase II/III clinical trials of ivonescimab covering 40 indications including lung cancer, biliary tract cancer, head and neck squamous carcinoma, triple negative breast cancer, colorectal cancer, and pancreatic cancer. Currently, 15 Phase III trials of ivonescimab are ongoing, including 5 global MRCTs and 9 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.

ABOUT 開坦尼® (CADONILIMAB, PD-1/CTLA-4)

開坦尼® (cadonilimab, PD-1/CTLA-4), is a first-in-class PD-1/CTLA-4 bispecific immunotherapy drug independently developed by the Company. 開坦尼® received NMPA approval in June 2022 for the treatment of patients with recurrent or metastatic cervical cancer who had failed prior platinum-based chemotherapy. In September 2024, it was approved for a new indication as a first-line treatment for locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. In May 2025, it was approved for another new indication as a first-line treatment for persistent, recurrent or metastatic cervical cancer. All three indications have been included in the latest NRDL. The Company is conducting over 40 Phase II/III clinical trials of cadonilimab covering more than 20 indications including gastric cancer, lung cancer, liver cancer, cervical cancer, and pancreatic cancer. Currently, 12 Phase III/pivotal trials of cadonilimab are ongoing, including 2 global Phase III/pivotal studies. Cadonilimab has demonstrated groundbreaking clinical value across dozens of clinical studies and real-world treatments involving over 120,000 patients.

ABOUT LIGUFALIMAB (AK117, CD47 MAB)

Ligufalimab is a next-generation CD47 monoclonal antibody independently developed by the Company. Global clinical trials in both solid tumors and hematologic malignancies are currently ongoing. Ligufalimab is the world's first CD47 monoclonal antibody to enter a registrational Phase III clinical study in solid tumors. In combination with ivonescimab or cadonilimab, ligufalimab has initiated more than 10 clinical studies across more than 8 solid tumor indications, including head and neck squamous cell carcinoma, pancreatic cancer, gastric cancer, biliary tract cancer, and colorectal cancer, with three China/global registrational Phase III studies currently ongoing. In hematologic malignancies, multiple China/global Phase II studies are ongoing for indications including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

By order of the Board

Akeso, Inc.

Dr. XIA Yu

Chairwoman and executive director

Hong Kong, June 1, 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.