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

RESULTS OF PHASE II CLINICAL TRIAL OF IVONESCIMAB (PD-1/VEGF BI-SPECIFIC ANTIBODY, AK112) IN COMBINATION OF CHEMOTHERAPY IN ADVANCED NON-SMALL CELL LUNG CANCER PUBLISHED AT THE 2022 ASCO ANNUAL MEETING

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 phase II clinical trial of Ivonescimab (PD-1/VEGF bi-specific antibody, research and development code: AK112), independently developed by the Company, in combination of chemotherapy in advanced non-small cell lung cancer (NSCLC) were published at the American Society of Clinical Oncology (ASCO) Annual Meeting.

This was an open-label, multi-center and multi-cohort phase II clinical trial (Clinical Trial number: NCT04736823) with safety and objective response rate (ORR) as the primary endpoints. As of March 20, 2022, a total of 83 patients with advanced NSCLC had been treated with AK112 in combination with chemotherapy for up to 12 months and an average dosing time of 7.56 months.

AK112 in combination with chemotherapy demonstrated a favourable safety profile and better efficacy results compared to PD-1/PD-L1 antibody combined with chemotherapy +/- anti-angiogenic agents combination therapy in patients with advanced NSCLC.

- AK112 in combination with chemotherapy for advanced NSCLC showed favourable safety profile:

  — No significant difference in the incidences of treatment related adverse events (TRAEs) between the squamous and the non-squamous NSCLC patients (30.1% of enrolled patients had squamous NSCLC (SQ-NSCLC), of which 52% were central type SQ-NSCLC).

  — No serious anti-VEGF-related toxicities such as bleeding and perforation.

- AK112 in combination with chemotherapy showed better anti-tumor activity in advanced NSCLC patients in various sub-types compared to PD-1/PD-L1 antibody combined with chemotherapy +/- anti-angiogenic agents combination therapy:

  — In cohort 1 (previously untreated advanced NSCLC patients without EGFR/ALK alterations), efficacy results were encouraging with a more prominent efficacy advantage in squamous NSCLC patients:

    ✓ Among all patients, median progression-free survival (PFS) was not reached, and 6-month PFS rate was 78.8%.

    ✓ In patients with SQ-NSCLC, median follow-up time was 7.9 months, ORR was 77.8%, disease control rate (DCR) was 100%, and 6-month PFS rate was 83.3%. The preliminary results are encouraging compared to approved PD-1 combined with chemotherapy therapies.

  — In cohort 2 (advanced NSCLC patients who failed to prior EGFR-TKI therapy):

    ✓ ORR and DCR were 68.4% and 94.7% respectively.

    ✓ Median PFS was 8.2 months, 6-month PFS rate was 69.3%.

  — In cohort 3 (advanced NSCLC patients who failed in prior platinum-based doublet chemo with PD-1/PD-L1 therapy):

    ✓ ORR was 40.0%, DCR was 80.0%.

    ✓ Median PFS was 6.6 months, 6-month PFS rate was 51.1%.

There are currently no immunotherapy regimens approved globally for NSCLC patients with EGFR-mutated who failed to prior EGFR-TKI therapy, and who failed in prior platinum-based doublet chemo with PD-1/PD-L1 therapy. The Company is conducting a phase III clinical trial of AK112 plus chemotherapy versus chemotherapy in EGFR mutated advanced non-squamous NSCLC that failed in prior EGFR-TKI therapy (Clinical Trial number: NCT05184712). A phase III clinical trial of AK112 monotherapy versus Pembrolizumab monotherapy in the first-line treatment of NSCLC is also ongoing.

INFORMATION ABOUT IVONESCIMAB (PD-1/VEGF BI-SPECIFIC ANTIBODY, AK112)

Ivonescimab is a first-in-class and the first to enter phase III clinical trial PD-1/VEGF bi-specific antibody independently developed by the Company. Engineered with our unique Tetrabody technology, Ivonescimab blocks PD-1 binding to PD-L1 and PD-L2, and blocks VEGF binding to VEGF receptors. PD-1 antibody combined with VEGF blocking agents have shown robust efficacy in various tumor types (including renal cell carcinoma, non-small cell lung cancer and hepatocellular carcinoma). In view of the co-expression of VEGF and PD-1 in the tumor microenvironment, Ivonescimab, as a single agent to block these two targets, may block these two pathways more effectively and enhance the anti-tumor activity, as compared to combination therapy.

INFORMATION ABOUT THE COMPANY

The Company is a biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of new innovative antibody drugs that are affordable to patients worldwide. Since the Company's establishment, the Company has established an end-to-end comprehensive drug development platform (ACE Platform) and system, encompassing fully integrated drug discovery and development functions, including target validation, antibody drug discovery and development, CMC production process development, and GMP compliant scale production. The Company has also successfully developed a bi-specific antibody drug development technology (Tetrabody technology). The Company currently has a pipeline of over 30 innovative drugs for the treatment of major diseases like tumors, autoimmune diseases, inflammation and metabolism diseases, 15 of which have entered clinical stage, including two first-in-class bi-specific antibody drugs. Cadonilimab (PD-1/CTLA-4) and Ivonescimab (PD-1/VEGF). In August 2021, Penpulimab (Anniko®), the first differentiated PD-1 monoclonal antibody which is produced by the Company with its self-innovative research and development, is approved and launched into the market. The Company's vision is to become a global leading biopharmaceutical company through research and development of high efficacy and breakthrough new drugs that are first-in-class and best-in-class therapies.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

ALK	anaplastic lymphoma kinase
CMC	chemistry, manufacturing and controls processes in the development, licensure, manufacturing and ongoing marketing of pharmaceutical products
CTLA-4	cytotoxic T-lymphocyte-associated protein 4, which downregulates T-cells immune response to cancer cells
EGFR	epidermal growth factor receptor
GMP	the Good Manufacturing Practice, which comprise guidelines and regulations from time to time issued pursuant to the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) as part of quality assurance

PD-1	programmed cell death protein 1, an immune checkpoint receptor expressed on T-cells, B-cells and macrophages. The normal function of PD-1 is to turn off the T-cell mediated immune response as part of the process that discourages a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of T-cells attaches to certain proteins on the surface of a normal cell or a cancer cell, T-cells will turn off its ability to kill the cell
PD-L1	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of T-cells, causing the T-cells to turn off its ability to kill the cancer cell
PD-L2	PD-1 ligand 2, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of T-cells, causing the T-cells to turn off its ability to kill the cancer cell
PFS	progression-free survival
TKI	tyrosine kinase inhibitors
VEGF	vascular endothelial growth factor, a family of cytokines critical for the growth and development of cancer cells. There are three main VEGF receptors and subtypes of VEGFs, including VEGFR-1, VEGFR-2 and VEGFR-3

Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that the Ivonescimab (PD-1/VEGF bi-specific antibody, AK112) will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board
Akeso, Inc.
Dr. XIA Yu
Chairwoman and executive director

Hong Kong, June 6, 2022

As at the date of this announcement, the Board of the Company 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.