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

APPROVAL OF COMMENCEMENT OF PHASE IB/II CLINICAL TRIAL OF IVONESCIMAB (PD-1/VEGF, AK112) COMBINED WITH DREBUXELIMAB (CD73, AK119) FOR THE TREATMENT OF ADVANCED SOLID TUMORS

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 the commencement of Phase Ib/II clinical trial company's in-house developed First-in-class bi-specific antibody drug, Ivonescimab (PD-1/VEGF, AK112), combined with Drebuxelimab (CD73, AK119) for the treatment of advanced solid tumors has been approved by the National Medical Products Administration (NMPA).

AK112 is the first PD-1/VEGF bi-specific antibody in the global which entered Phase III clinical research. The combination therapy of PD-1 antibody and VEGF blocker has shown strong efficacy in various tumor types. AK119 targets the key node of CD73 through adenosine pathway, and its inhibitor has broad therapeutic prospects for tumors which are quite sensitive to the adenosine pathway. Combination with immune checkpoint drugs such as AK112 can strengthen the synergistic effect of tumor therapy.

AK119 combined with AK112 has demonstrated well in vivo pharmacodynamic activity and safety in relevant pre-clinical studies. This unique combination therapy strategy will bring new breakthrough in tumor therapy.

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.

Currently, the Company is conducting a phase III clinical trial of AK112 monotherapy versus Pembrolizumab monotherapy as the first-line treatment for NSCLC patients with positive PD-L1 expression. In addition, 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 is ongoing. AK112 has started multiple clinical trials for various stages treatment of indications including non-small cell lung cancer and small cell lung cancer.

INFORMATION ABOUT DREBUXELIMAB (CD73, AK119)

Drebuxelimab is a humanized monoclonal antibody self-developed by the Company with a unique mechanism to activate B-cells to generate immune responses to tumor antigens and viruses. It can significantly inhibit the enzymatic activity of CD73 and block the production of immunosuppressive adenosine. At present, there is no similar product successfully developed and commercialized in the global market.

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 global first bi-specific antibody drugs. 開坦尼® (Cadonilimab) and Ivonescimab (PD-1/VEGF). In August 2021, Anniko® (Penpulimab), the first differentiated PD-1 monoclonal antibody which is produced by the Company with its self-innovative research and development, was approved and launched into the market. In June 2022, 開坦尼® (Cadonilimab) was approved for launching into market for the treatment of patients with R/M CC. 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 of the world.

CD73	ecto-5'-nucleotidase
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
R/M CC	recurrent or metastatic cervical cancer
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 Ivonescimab (PD-1/VEGF bi-specific antibody, AK112) and Drebuxelimab (CD73, AK119) 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, October 14, 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.