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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

PD-1/VEGF BI-SPECIFIC ANTIBODY (AK112) OBTAINED APPROVAL TO INITIATE A PHASE II CLINICAL TRIAL FOR MONOTHERAPY OR COMBINED CHEMOTHERAPY NEOADJUVANT/ADJUVANT THERAPY OF RESECTABLE NON-SMALL CELL LUNG CANCER

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 PD-1/VEGF bi-specific antibody (research and development code: AK112), the novel immuno-oncology drug independently developed by the Company, obtained approval from the Center for Drug Evaluation (CDE) of the National Medical Products Administration of the People’s Republic of China to initiate a phase II clinical trial for monotherapy or combined chemotherapy neoadjuvant/adjuvant therapy of resectable non-small cell lung cancer (“**NSCLC**”).

This is an open and multi-center phase II randomized clinical trial aiming to evaluate whether pre-operative AK112 monotherapy or combined chemotherapy neoadjuvant/adjuvant therapy can improve the surgical pathological remission rate for patients with resectable NSCLC.

Lung cancer is one of the cancers with the highest morbidity and mortality in the world, of which about 85% are NSCLC, and about 30% of patients belong to resectable early and mid-stage NSCLC when they are first diagnosed. Certain clinical trials have shown that neoadjuvant immunotherapy can play an important role in the comprehensive treatment of early stage NSCLC, with controllable adverse reactions and less surgery delay.

Currently, the consensus of NSCLC neoadjuvant immunotherapy is: patients with resectable phase IB-III A NSCLC may consider neoadjuvant immunotherapy combined with platinum-containing dual-agent chemotherapy or neoadjuvant immune monotherapy before surgery. The efficacy of immunotherapy combined with chemotherapy is better than chemotherapy with controllable safety, but the improvement of pathological remission rate is limited. Immune checkpoint inhibitors plus anti-angiogenic drugs have been synergistically observed in multiple tumor types, PD-1/VEGF bi-specific antibody combined with chemotherapy is therefore expected to obtain better clinical benefits.

AK112 has shown good safety and tolerability in early clinical trials on various types of lung cancers including NSCLC and small cell lung cancer (“SCLC”), and has also shown excellent anti-tumor effects.

AK112 is the world’s leading drug which entered phase III clinical trial among the same type of drugs. AK112 is another first-in-class bi-specific antibody drug developed by the Company to enter advanced clinical stage after the first-in-class Cadonilimab (PD-1/CTLA-4 bi-specific antibody, research and development code: AK104) entered the review stage. In addition, the registrational phase III clinical trial of AK112 for the treatment of NSCLC after treatment failure by epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI) has been initiated; the phase III clinical trial of AK112 for the first-line treatment of driver-gene negative PD-L1 positive NSCLC and the phase III clinical trial of AK112 for the first-line treatment of extensive stage SCLC are about to be initiated.

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

AK112 is a first-in-class and the first to enter clinical trial PD-1/VEGF bi-specific antibody independently developed by the Company. Engineered with our unique Tetrabody technology, AK112 blocks PD-1 binding to PD-L1 and PD-L2, and blocks VEGF binding to VEGF receptors. PD-1 antibody in combination 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 the view of the co-expression of VEGF and PD-1 in the tumor micro environment, AK112, 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 20 innovative drugs for the treatment of major diseases like tumors, autoimmune diseases, inflammation and metabolism diseases, 13 of which have entered clinical stage, including two first-in-class bi-specific antibody drugs

(PD-1/CTLA-4 and PD-1/VEGF). 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

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 cell immune response to cancer cells
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 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 the T cell that causes the T cell 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 the T cell that causes the T cell to turn off its ability to kill the cancer cell
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 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, November 2, 2021

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, Mr. XIE Ronggang and Dr. ZHOU Yi as non-executive directors, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.