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)

INSIDE INFORMATION ANNOUNCEMENT

THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION APPROVES MARKETING APPROVAL OF ANNIKO® (PENPULIMAB) COMBINED WITH CHEMOTHERAPY AS THE FIRST LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC SQUAMOUS NSCLC

This announcement is made by Akeso, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09 of the Rules (the "**Listing Rules**") Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The board of directors of the Company (the "**Board**") announces that the anti PD-1 monoclonal antibody drug Anniko® (penpulimab), co-developed by the Company with Sino Biopharmaceutical Limited (stock code: 1177.HK) (together with its subsidiaries "**Sino Biopharm**"), combined with chemotherapy as the first line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sq-NSCLC) has been granted marketing approval by the National Medical Products Administration (NMPA) of the People's Republic of China ("**China**").

The approval of new indication is based on a randomized, double-blind, multi-center phase III clinical trial (AK105-302, NCT03866993), with 350 locally advanced or metastatic sq-NSCLC patients who have not received prior systemic therapy. According to the trial results published on 2022 ESMO Immuno-Oncology, penpulimab combined with chemotherapy shows consistent efficacy benefits across all efficacy endpoints and significantly reduces the risk of disease progression and death.

- The median progression-free survival (mPFS) of the treatment group (7.6 months) is significantly superior to the placebo +chemo group (4.2 months).

- The objective response rate (ORR) of the treatment group (71.4%) is significantly higher than the placebo +chemo group (44.0%).

In terms of safety, the treatment group shows no difference in the incidence of adverse event (AE) and serious adverse event (SAE), which shows the favourable safety profile of penpulimab.

Lung cancer is a malignant tumor with high incidence and high mortality rate worldwide. The incidences of lung cancer around the world and in China have exceeded 2.2 million and 810 thousand respectively in 2020. NSCLC patients accounts for 85% of total lung cancer patients, and about 30% of NSCLC patients are sq-NSCLC. The NMPA's approval of Anniko® combined with chemotherapy as the first line treatment of locally advanced or metastatic sq-NSCLC will further expand its potential. In April 2022, this therapy was included as Grade II recommendation in Guidelines for Non-Small Cell Lung Cancer Treatment (2022) of Chinese Society of Clinical Oncology (CSCO) and was included in Guidelines of Chinese Society of Clinical Oncology Immune Checkpoint Inhibitor Clinical Practice (2022).

INFORMATION ABOUT ANNIKO®（PENPULIMAB）

Anniko® (penpulimab) is a new PD-1 monoclonal antibody with IgG1 subtype and Fc segment modification, which is structurally stable and less prone to aggregation. Antibody-dependent cell-mediated cytotoxicity (ADCC), acoustic doppler current profiler (ADCP) and complement dependent cytotoxicity (CDC) is avoided entirely, and antibody-drug conjugate reaction (ADCR) is lessen. Crystal structure analysis reveals a unique PD-1 binding epitope with a slower dissociation rate from PD-1 for durable blockade of PD-1/PD-L1 binding. This differentiation may lead to a better efficacy and safety profile for the Penpulimab. In August 2021, Anniko® (Penpulimab) received marketing approval from the NMPA and launched into the market for the treatment of relapsed or refractory classic Hodgkin's lymphoma after at least second-line chemotherapy treatment. In January 2023, Anniko® combined with chemotherapy as the first line treatment of locally advanced or metastatic sq-NSCLC received marketing approval from the NMPA as new indication.

INFORMATION ABOUT THE COMPANY

The Company is a commercial-stage biopharmaceutical company committed to the discovery, development, manufacturing and commercialization of innovative medicines with high unmet medical needs worldwide. Founded in 2012, the Company has established a comprehensive in-house drug development platform (ACE Platform) and know-how, including R&D, clinical development, CMC (Chemistry, Manufacturing, and Controls), and commercialization capabilities. With fully integrated multi-functional platform, the Company is internally working on a robust pipeline of over 30 innovative assets in the fields of cancer, autoimmune disease, inflammation, metabolic disease, and other major therapeutic areas, among which 17 assets have entered to clinical stage. Leveraging the Company's in-house developed bispecific platform technology ("**Tetrabody technology**"), the Company has advanced four potential first-in-class bispecific antibody drugs into market or clinical development, including cadonilimab (PD-1/CTLA-4), ivonescimab (PD-1/VEGF), PD-1/LAG-3, and TIGIT/TGF-β bispecific antibodies. In June 2022, 開坦尼® (cadonilimab) was approved by the NMPA and became the first commercialized PD-1 based bispecific drug globally. Anniko® (penpulimab), the Company's internally discovered and developed PD-1 antibody, was granted marketing approval in China in August 2021. The Company is listed on the Main Board of the Stock Exchange.

INFORMATION ABOUT SINO BIOPHARM

Sino Biopharm, listed on Stock Exchange (1177.HK) and included in Hang Seng Index, is a leading R&D-based pharmaceutical group in China, with business covering the entire industry chain including various pharmaceutical R&D platforms, intelligent production and strong sales system. Its products include various kinds of biopharmaceutical and chemical medicines, and have gained a competitive foothold in various therapeutic categories with promising potentials, including tumors, liver diseases, cardiocerebral diseases, analgesic medicines, respiratory system medicines and orthopedic diseases.

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	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
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 Listing Rules: There is no assurance that Anniko® (penpulimab) will ultimately be successfully commercialized 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, January 16, 2023

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.