**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

## IVONESCIMAB(PD-1/VEGF, AK112) WAS GRANTED THREE BREAKTHROUGH THERAPY DESIGNATIONS BY CENTER FOR DRUG EVALUATION(CDE) OF THE NMPA

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 Ivonescimab (PD-1/VEGF, AK112), the Company's in-house developed first-in-class bi-specific antibody, was granted three breakthrough therapy designations by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA). These three designations include:

- AK112 combined with chemotherapy for the treatment of EGFR-mutated locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) patients who have failed to EGFR-TKI treatment, which has completed Phase III clinical trial patient enrollment recently.

- AK112 as the first-line treatment for locally advanced or metastatic NSCLC patients with positive PD-L1 expression, which has entered into Phase III clinical trial.

- AK112 combined with docetaxel for the treatment of locally advanced or metastatic NSCLC patients who failed to prior PD-(L)1 inhibitor combined with platinum-based doublet chemotherapy, which is the only innovative drug candidate which obtained breakthrough therapy designation in PD-(L)1 resistant lung cancer treatment area in China.

Breakthrough therapy designation aims to accelerate new drug development. These drugs are designed to treat severe diseases and have shown encouraging results in early clinical studies. These drugs have a significant improvement in clinical endpoints over existing therapies or when there are unmet medical needs. The Company believes that these three designations of AK112 in several NSCLC studies will definitely accelerate its R&D and marketing progress.

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 70% of NSCLC patients are diagnosed at advanced stages. ''Immunotherapy plus anti-angiogenesis'' therapy has proved its combination advantages in previous studies worldwide, lung cancer is one of the mainstream exploration areas of this therapy. AK112 could simultaneously block PD-1 and VEGF targets and has demonstrated favourable safety profile and promising anti-tumor efficacy in recent studies conducted by the Company. AK112 is expected to provide a comprehensive and effective therapy for the treatment of NSCLC.

## 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 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.

## DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

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| CMC | chemistry, manufacturing and controls processes in the development, licensure, manufacturing and ongoing marketing of pharmaceutical products |
| 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 |
| IRRC | independently regulatory review commission |
| 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) 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 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.*