

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**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**

### **RESULTS OF PHASE IB/II CLINICAL TRIAL OF IVONESCIMAB (PD-1/VEGF BI-SPECIFIC ANTIBODY, AK112) MONOTHERAPY FOR 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 Ib/II clinical trial of Ivonescimab (PD-1/VEGF bi-specific antibody, research and development code: AK112), independently developed by the Company, as a monotherapy for advanced non-small cell lung cancer (NSCLC) were published at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting.

This trial was a multi-center and open-label clinical trial (Clinical Trial number: NCT04900363). The dose-selection part was divided into four different dosing regimens including 10 mg/kg Q3W, 20 mg/kg Q2W, 20 mg/kg Q3W or 30 mg/kg Q3W, with safety and objective response rate (ORR) as the primary endpoints. As of March 4, 2022, 96 patients were enrolled, 90 of whom had at least one post-treatment tumor assessment.

#### **Summary of the clinical results:**

- AK112 was safe and well tolerated in advanced NSCLC, with no significant difference between squamous NSCLC (SQ-NSCLC) and non-squamous NSCLC (NSQ-NSCLC) patients.
  - The incidence rate of grade 3~4 treatment related adverse events (TRAE) was 13.5%, with no TRAE leading to permanent treatment discontinuation.

- Among 54 treatment-naïve patients with PD-L1 positive (PD-L1 TPS $\geq$ 1%) who had at least one post-treatment tumor assessment, the ORR was 50.0% and disease control rate (DCR) was 96.3%.
- Among treatment naïve 50 patients receiving AK112 $>$ 10 mg/kg Q3W, AK112 presented encouraging anti-tumor efficacy in different PD-L1 expression levels:
  - In patients with PD-L1 positive patients (TPS $\geq$ 1%), ORR was 60.0% and DCR was 97.1%.
  - In patients with TPS 1%~49%, ORR was 50.0% and DCR was 95.5%.
  - In patients with TPS $\geq$ 50%, ORR was 76.9% and DCR was 100.0%.

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 (NCT05184712) is 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<sup>®</sup>), 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 of the world.

## **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-cells immune response to cancer cells
DCR	Disease Control Rate
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
TKI	tyrosine kinase inhibitors
TPS	tumor proportion score
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.*