

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

SIX LATEST RESEARCH RESULTS TO BE PUBLISHED AT THE SITC 2021

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 Company will publish three clinical trials results on Cadonilimab (PD-1/CTLA-4 bi-specific antibody, research and development code: AK104) for treating nasopharyngeal carcinoma and PD-1/VEGF (research and development code: AK112) for treating ovarian cancer, as well as three mechanism studies results on Cadonilimab (PD-1/CTLA-4 bi-specific antibody, research and development code: AK104), CD47 (research and development code: AK117) and CD73 research and development code: AK119) at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (“**SITC 2021**”).

Three clinical trials are as follows:

No. Research title

- 1 A phase II study of AK104, a bi-specific antibody targeting PD-1 and CTLA-4, in patients with metastatic nasopharyngeal carcinoma (NPC) who had progressed after two or more lines of chemotherapy
- 2 Efficacy and safety of AK112, an anti-PD-1/VEGF bi-specific antibody, in patients with platinum-resistant epithelial ovarian cancer in a phase I study
- 3 A phase Ib/II clinical study of AK112, a PD-1/VEGF bi-specific antibody, in combination with olaparib in BRCA germline wild-type platinum sensitive recurrent ovarian cancer

Three mechanism studies are as follows:

No. Research title

- 1 Cadonilimab, an anti-PD-1/CTLA-4 bi-specific antibody with Fc effector null backbone
- 2 AK117, a CD47 blocking antibody with robust macrophage activation without red blood cell hemagglutination
- 3 AK119, a CD73 targeting antibody with dual mechanism of action

INFORMATION ABOUT CADONILIMAB (PD-1/CTLA-4 BI-SPECIFIC ANTIBODY, AK104)

Cadonilimab (AK104) is a novel, potential next-generation, first-in-class bi-specific PD-1/CTLA-4 immuno-oncology backbone drug independently developed by the Company, and its major indications include liver cancer, cervical cancer, lung cancer, gastric cancer, esophageal squamous cell cancer and nasopharyngeal carcinoma. The preliminary research data of cervical cancer, gastric cancer and other tumors shows that, as compared with the combination therapy of PD-1 and CTLA-4, Cadonilimab has much lower toxicity and demonstrated promising safety profile and efficacy. Cadonilimab has been incorporated in the Major New Drug Innovation Program under the 13th Five-year Plan for Major Technology Project (十三五「重大新藥創製」科技重大專項支持專案) issued by the National Health Commission and Ministry of Science and Technology in 2017 and has been enlisted in the 2017 Pearl River Talent Program of Guangdong Province — Introduction of Innovation and Entrepreneurship Team Support Program (2017年廣東省「珠江人才計劃」引進創新創業團隊支持專案). It was also jointly rated by the China Medical Biotechnology Association and Chinese Medicinal Biotechnology as one of the 2017 Top Ten Medicinal Biotechnology Advancements in China (2017年中國醫藥生物技術十大進展).

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 AK117 (CD47 MONOCLONAL ANTIBODY)

AK117 is a novel humanized IgG4 mAb independently developed by the Company. It can bind with CD47 expressed on tumor cells to prevent the interaction between CD47 and its receptor, SIRP α , expressed on macrophages so as to enhance phagocytosis to inhibit the growth of tumor cells. Previously published data demonstrated exceptional safety profile. AK117 resulted in no dose-limiting toxicity and no anemia of clinical significance in subjects in all dose escalation cohort (the highest dose cohort was 45 mg/kg once-weekly), and was well tolerated by subjects in all cohorts. The CD47 receptor occupancy rate (RO) of the peripheral blood T cells has reached and maintained at 100% in the 3 mg/kg cohort.

INFORMATION ABOUT AK119 (CD73 MONOCLONAL ANTIBODY)

As a full antagonist of CD73 activity, AK119 completely blocks CD73 activity, causes B cell activation and enhances antibody production. Enhanced antibody production in Novel Coronavirus (“**COVID-19**”) patients may potentially augment their ability to destroy SARS-CoV-2 virus. Therefore, AK119 could potentially be the effective treatment to be used for COVID-19 illness. AK119 may also result in stronger immunity to SARS-CoV-2 virus, and potentially be used in conjunction with vaccination of healthy people to enhance the efficacy of vaccines.

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

BRCA	breast cancer gene
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
Fc	fragment crystallizable
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 Cadonilimab (AK104), PD-1/VEGF bi-specific antibody (AK112), CD47 monoclonal antibody (AK117) and CD73 monoclonal antibody (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 18, 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.