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

PENPULIMAB MONOCLONAL ANTIBODY (PD-1) IS SELECTED UNDER THE NEW POLICY OF REAL-TIME ONCOLOGY REVIEW (RTOR) OF THE FDA AND BLA ALREADY SUBMITTED IN THE UNITED STATES FOR TREATMENT OF THIRD-LINE NASOPHARYNGEAL CARCINOMA

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**") is pleased to announce that Penpulimab (research and development code: AK105), an PD-1 monoclonal antibody drug co-developed by the Company with Sino Biopharmaceutical Limited (stock code: 1177.HK) (together with its subsidiaries, "**Sino Biopharm**"), has submitted a Biologics License Application ("**BLA**") to the Food and Drug Administration of the United States ("**FDA**") for third-line treatment of metastatic nasopharyngeal carcinoma.

The BLA will be reviewed under the new policy of Real-Time Oncology Review ("**RTOR**"). RTOR is a major and innovative new oncology drug approval policy issued by the Oncology Center of Excellence ("**OCE**") of the FDA. It is faster than the priority review and aims to accelerate the process of drug approval, so as to facilitate a safe and effective treatment of cancer patients as early as possible.

Penpulimab has received breakthrough therapy designation from the FDA for third-line treatment of metastatic nasopharyngeal carcinoma. With this BLA submitted under RTOR, the Company expected such differential PD-1 monoclonal antibody developed by the Company can quickly satisfy the needs of patients with nasopharyngeal carcinoma in the world.

INFORMATION ABOUT PENPULIMAB (PD-1 MONOCLONAL ANTIBODY, AK105)

Penpulimab (PD-1 monoclonal antibody, AK105) is jointly developed and commercialized by a joint venture established by the Company and Chia Tai-Tianqing Pharmaceutical Group Co., Ltd. ("**Chia Tai-Tianqing**"), a subsidiary of Sino Biopharm. Penpulimab's fragment crystallisable ("**Fc**") receptor and complement mediated effector are completely removed by mutations of Fc region, it also has a slower antigen binding offrate compared with the PD-1 antibodies that are already launched in foreign market. These features have made Penpulimab more effective in blocking the activity of the PD-1 pathway and evaded the T-cell anti-tumor activity, thus it has the potential to become an anti-PD-1 drug that can achieve better clinical efficacy.

INFORMATION ABOUT RTOR

In order to ensure the timeliness, safety and effectiveness of drugs for cancer patients, and to maintain and enhance the review and approval quality, the OCE of the FDA has introduced RTOR, a more efficient review and approval process for major and innovative new oncology drug. Companies adopted by the RTOR will be guided by the FDA, which can greatly shorten the time for review and increase the probability of approval.

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 ("**R&D**") of high efficacy and breakthrough new drugs that are first-in-class and best-in-class therapies.

INFORMATION ABOUT SINO BIOPHARM

Sino Biopharm 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.

INFORMATION ABOUT CHIA TAI-TIANQING

Chia Tai-Tianqing is an innovative pharmaceutical company with integrated R&D, manufacturing and sales capabilities. It is a renowned R&D and manufacturing base in China targeting drugs on liver diseases and oncology treatment. It is a key high technology enterprise, as well as the highlighted Lianyungang new medical industry base under the State Torch Program. It ranked 16th on the list of the "Top 100 Pharmaceutical Enterprises in China" in 2018, and was the Chinese pharmaceutical enterprise with the best drug pipeline in 2019 (by the China National Pharmaceutical Industry Information Center).

With more than 12,000 employees, Chia Tai-Tianqing's products focus on six core therapeutic areas, including oncology, liver diseases, respiratory diseases, infection, endocrine and cardiocerebral. Apart from liver diseases, Chia Tai-Tianqing has formed its unique product line in the oncology field. "Anlotinib Hydrochloride Capsules", a category 1 new drug, has been proven to treat three major indications including non-small cell lung cancer, small cell lung cancer and soft tissue sarcoma. It was a designated Orphan Drug for treatment of ovarian cancer and soft tissue sarcoma by the FDA. Multiple clinical trials are ongoing for other indications.

Chia Tai-Tianqing has over 1,500 R&D staff. It invests 10% to 12% of its annual sales revenue in R&D every year. There are more than 250 projects in its product pipeline.

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
VEGF	vascular endothelial growth factor, a family of cytokines critical for the growth and development of cancer cells. There are three main subtypes of VEGFs and VEGF receptors, 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 Penpulimab (PD-1 monoclonal antibody, AK105) 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, May 24, 2021

As at the date of this announcement, the Board 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.