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

NEW DRUG APPLICATION FOR PENPULIMAB MONOCLONAL ANTIBODY (PD-1) FOR THIRD-LINE TREATMENT OF METASTATIC NASOPHARYNGEAL CARCINOMA ACCEPTED BY 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**") is pleased to announce that the new drug application ("**NDA**") of Penpulimab (research and development code: AK105), a PD-1 monoclonal antibody drug co-developed by the Company with Sino Biopharmaceutical Limited (stock code: 1177.HK) (together with its subsidiaries "**Sino Biopharm**"), for third-line treatment of metastatic nasopharyngeal carcinoma, had been submitted and was accepted by the National Medical Products Administration (the "**NMPA**") of the People's Republic of China ("**China**"). This is the fourth indication of Penpulimab of which the NDA was successfully submitted in China and the United States of America. Prior to that, Penpulimab has submitted two NDAs in China and one biologics license application ("**BLA**") in the United States of America.

Penpulimab is a new PD-1 monoclonal antibody that applies the immunoglobulin G1 ("**IgG1**") subtype, modified by fragment crystallisable ("**Fc**") segment, which has a slower antigen binding offrate. Analysis shows that its crystal structure has unique binding epitope which continuously blocked the binding of PD-1/PD-L1, thus differentiates it from other PD-1 products in the market, which allows Penpulimab to enhance its immunotherapy efficacy and reduce immune-related adverse effects.

Nasopharyngeal carcinoma is a malignant tumor with a high incidence in localized areas. Patients with recurrent or metastatic nasopharyngeal carcinoma have a poor prognosis, with a median overall survival period of less than 20 months, and no effective treatment option is available after failure of second-line therapy. Penpulimab has demonstrated a considerably high rate of sustained tumor remission and longer survival benefit in patients with metastatic nasopharyngeal carcinoma who have failed prior multiline therapy, and its efficacy in patients with refractory nasopharyngeal carcinoma with liver metastases is impressive. Penpulimab has been proved safe and well-tolerated, with a low incidence of overall immune-related adverse effects. The Company anticipates the approval of Penpulimab will provide patients with better treatment options.

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 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 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 Food and Drug Administration of the United States. Multiple clinical trials are ongoing for other indications.

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

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 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
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
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, August 5, 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.