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

FDA APPROVED ANNIKO® (PENPULIMAB-KCQX, PD-1) IN TWO INDICATIONS FOR COMPREHENSIVE TREATMENT OF ADVANCED 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 the U.S. Food and Drug Administration (FDA) has approved the Company's differentiated PD-1 monoclonal antibody, penpulimab-kcqx, in combination with cisplatin or carboplatin and gemcitabine for the first-line treatment of adult recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC). FDA also approved penpulimab-kcqx as a single agent for adults with metastatic non-keratinizing NPC with disease progression on or after platinum-based chemotherapy and with least one other prior line of therapy. Penpulimab-kcqx was developed independently by the Company, with further development and commercialization managed through a joint venture with Chia Tai-Tianqing Pharmaceutical Group.

Penpulimab-kcqx has already been approved in China for two indications: 1. first-line treatment of advanced NPC, and 2. second or later line treatment of advanced NPC. The FDA approval is based on the international Phase III clinical trial AK105–304 (NCT 04974398) and the pivotal AK105–202 (NCT03866967), which supported the two Biologics License Application (BLA) for penpulimab-kcqx.

AK105–304 is a randomized, double-blind, international Phase III trial. The data will be presented at the 2025 American Association for Cancer Research (AACR) Annual Meeting.

Previously, the FDA granted penpulimab-kcqx Breakthrough Therapy Designation (BTD), Orphan Drug Designation (ODD), and Fast Track Designation (FTD) for NPC treatment, highlighting the critical unmet need for this therapy. The recent FDA approval of penpulimab-kcqx offers a new, immunotherapy option for advanced NPC patients in US.

According to the WHO 2020 Global Cancer Statistics, over 133,000 new NPC cases are diagnosed annually worldwide, with more than 70% of the patients presented with locally advanced disease. Recurrent or metastatic NPC has a poor prognosis and limited survival. Penpulimab-kcqx's FDA approval will expand the number of NPC patients that can benefit from its treatment.

The press release regarding the FDA approval of penpulimab-kcqx's is available on their website:
https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-penpulimab-kcqx-non-keratinizing-nasopharyngeal-carcinoma

ABOUT ANNIKO® (PENPULIMAB, PD-1)

ANNIKO is the only novel differentiated PD-1 monoclonal antibody utilizing the IgG1 subtype with Fc engineering, demonstrating enhanced efficacy in immunotherapy while minimizing adverse reactions. Currently, penpulimab has been granted marketing approval by NMPA as treatment for recurrent or refractory classical Hodgkin lymphoma and for locally advanced or metastatic squamous non-small cell lung cancer. Besides, penpulimab for treatment for 1L NPC and for metastatic non-keratinizing NPC with disease progression on or after platinum-based chemotherapy and with least one other prior line of therapy have been approved by both NMPA and US FDA.

By order of the Board
Akeso, Inc.
Dr. XIA Yu
Chairwoman and executive Director

Hong Kong, April 25, 2025

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 Dr. ZHANG Peng as executive directors, Mr. XIE Ronggang as non-executive director, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.