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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

LATEST STUDY OF PENPULIMAB MONOCLONAL ANTIBODY (PD-1) IN COMBINATION WITH ANLOTINIB FOR 1L ADVANCED HCC PUBLISHED AT THE 2021 ASCO GI

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 latest study of Penpulimab (安尼可) (research and development code: AK105), an anti-PD-1 monoclonal antibody drug co-developed by the Company and Sino Biopharmaceutical Limited (stock code: 1177.HK) in combination with Anlotinib for treatment of 1L advanced hepatocellular carcinoma (“**HCC**”) has been published at the Gastrointestinal Cancers Symposium 2021 (“**2021 ASCO GI**”).

As of November 2020, the confirmed objective response rate (ORR), disease control rate (DCR), the median progression-free survival (“**PFS**”) and 6-month PFS of Penpulimab in combination with low dosage of Anlotinib (8 mg, 2 weeks-on, 1 week-off) for treatment of 1L HCC were 31.0%, 82.8%, 8.8 months and 63.2%, respectively. The median overall survival (“**OS**”) has not been reached and the 6-month OS rate was 93.2%. The incidence Grade 3 or higher treatment-related adverse events (TRAE) and serious adverse events in relation to Penpulimab or Anlotinib were 19.4% and 6.5%, respectively.

According to the study, the combination of Penpulimab and Anlotinib is safe and tolerable, and has demonstrated encouraging anti-tumor activity for treatment of 1L advanced HCC patients. In addition, the results of the study support the exploration of combination of Penpulimab and higher dosage of Anlotinib. The Phase III clinical trial of the combination of Penpulimab and Anlotinib (10 mg, 2 weeks-on, 1 week-off) for treatment of 1L advanced HCC (NCT04344158) is ongoing.

In May 2020, the National Medical Products Administration of the People's Republic of China (NMPA) has accepted the new drug application of Penpulimab for the treatment of patients with classical Hodgkin's lymphoma (cHL) that has relapsed or refractory (r/r) after two or more lines of systemic chemotherapy (r/r cHL). The registrational clinical trial for third-line metastatic nasopharyngeal cancer with Penpulimab has also met primary endpoints in objective response rate (ORR) assessed by independent radiological review. Currently, Penpulimab may be applied to major indications such as liver cancer, gastric cancer, lung cancer, etc. Clinical trials for Penpulimab in combination with Anlotinib for tumors are under progress.

INFORMATION ABOUT PENPULIMAB (安尼可)

Penpulimab (AK105, PD-1 monoclonal antibody) 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 Biopharmaceutical Limited (stock code: 1177.HK) (together with its subsidiaries "**Sino Biopharm**"). Penpulimab is the only new drug that can be used by Sino Biopharm for the development of monotherapy or combination therapy based on PD-1 antibody, which is possibly one of the most innovative PD-1 monoclonal antibody drug candidates of the Company in advanced clinical development stage that can be differentiated from other products. 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 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.

INFORMATION ABOUT SINO BIOPHARM

Sino Biopharm is a leading research and development (“**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 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% to 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

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 cancer cell
cHL	classical Hodgkin's lymphoma, a type of cancer arising from the lymphatic system
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

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 Penpulimab (AK105, PD-1 mAb) 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, January 20, 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.