ST to Commercialise New Anti-PD1 Antibody

Specialised Therapeutics signs partnership agreement with Akeso Inc. and CTTQ-Akeso to commercialise new anti-PD1 antibody in Australia and Southeast Asia

Singapore and Beijing, China, 12 April 2023: Independent biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) will partner with CTTQ-Akeso (Shanghai) Biomed. Tech. Co., Ltd. (CTTQ-Akeso) jointly established by Akeso, Inc. (9926.HK, Akeso) and Chia Tai Tianqing Pharmaceutical Group Co., Ltd. to commercialise a new immuno-oncology therapy in Australia, Singapore and across Southeast Asia.

The therapy ANNIKO® (penpulimab) is an anti-PD1 monoclonal antibody currently under regulatory review by the US FDA for nasopharyngeal carcinoma – a difficult to treat form of head and neck cancer.

This follows the FDA granting ANNIKO orphan drug and fast track designations in 2020, as well as a further "breakthrough therapy" designation in March 2021. In addition, ANNIKO was granted a FDA Real-Time Oncology Review (RTOR) in 2021, to accelerate the drug approval process.[1],[2]

ANNIKO has been approved in China for the treatment of adult patients with relapsed or refractory classical Hodgkin's lymphoma (advanced r/r cHL) who have undergone at least second-line chemotherapy, as well as first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sq-NSCLC) in combination with chemotherapy.[3]

Under the terms of the arrangement, ST will be responsible for all marketing, regulatory and distribution activities in its key regions of Australia, Singapore and across Southeast Asia.

CTTQ-Akeso retains the rights of conducting any development work in relation to ANNIKO and Akeso retains all rights to product manufacture and supply.

Announcing the partnership, ST Chief Executive Officer Carlo Montagner said ANNIKO was the first immuno-oncology drug to be included in the company's therapeutic portfolio and the arrangement was further endorsement of ST's regional capabilities.

"ANNIKO will provide a new opportunity for patients in our regions with nasopharyngeal carcinoma – a very difficult-to-treat cancer – to be treated with an immune-based therapy," he said.

"Nasopharyngeal carcinoma is native to Southeast Asia, affecting between 15 and 50 people in every 100,000[4] and with almost 37,000 new cases diagnosed annually in this region.[5] Making ANNIKO available for this disease is a high priority."

Akeso CEO Michelle Xia said the company looked forward to collaborating with ST and providing eligible cancer patients with world-class therapy.

"We trust that ST's expertise in these regions, navigating complex regulatory channels will ensure our therapy reaches as many eligible patients as possible," she said.

"We look forward to a successful and mutually beneficial partnership, working together with a shared goal of improving patient outcomes."

Regulatory activities are currently in progress.

Ends.

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout Southeast Asia, as well as in Australia and New Zealand. ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com.

About Akeso Inc.

Akeso Inc (HKEX: 09926) is a commercial-stage biopharmaceutical company committed to the discovery, development, manufacturing and commercialization of innovative medicines with high unmet medical needs worldwide. Founded in 2012, the company has established a comprehensive in-house drug development platform (ACE Platform) and know-how, including R&D, clinical development, CMC (Chemistry, Manufacturing, and Controls), and commercialization capabilities. With fully integrated multi-functional platform, Akeso is internally working on a robust pipeline of over 30 innovative assets in the fields of cancer, autoimmune disease, inflammation, metabolic disease, and other major therapeutic areas. 17 assets have entered into clinical stage. Akeso has advanced four potential first-in-class bispecific antibody drugs into market or clinical development, including cadonilimab (PD-1 / CTLA-4), ivonescimab (PD-1 / VEGF), PD-1 / LAG-3, and TIGIT / TGF-Beta bispecific antibodies. In June 2022, cadonilimab was approved by the NMPA and became the first commercialized PD-1 based bispecific drug globally. Another Akeso internally discovered and developed oncology product, penpulimab (a PD-1 antibody), was granted marketing approval in China in August 2021. Akeso is listed on the Main Board of the Stock Exchange of Hong Kong Limited.

About CTTQ-Akeso

CTTQ-Akeso (Shanghai) Biomed. Tech. Co., Ltd. (CTTQ-Akeso) is an innovative biomedical company jointly established by Akeso, Inc. (9926.HK) and Chia Tai Tianqing Pharmaceutical Group Co., Ltd. CTTQ-Akeso is focused on the R&D and commercialization of Penpulimab (安尼可®).

About Anniko® (penpulimab)

ANNIKO (penpulimab) is a humanised anti-programmed cell death 1 (PD-1) monoclonal antibody developed by Akeso Biosciences for the treatment of various cancers. ANNIKO is an immunoglobulin G1 monoclonal antibody uniquely engineered to completely eliminate Fcγ receptor binding and Fc-mediated effector functions that can compromise anti-tumour activity. ANNIKO is approved in China for the treatment of adult patients with relapsed or refractory classic Hodgkin's lymphoma (advanced r/r cHL) who have undergone at least second-line chemotherapy, as well as for Sq-NSCLC. The treatment for 1L sq-NSCLC in combination with chemotherapy has been included as a level II recommendation in the Chinese Society of Clinical Oncology (CSCO) Guidelines. The treatment for advanced r/r cHL has been included as a level I recommendation in the CSCO Guidelines. The treatment for advanced nasopharyngeal carcinoma (NPC) has been included as a level III recommendation in the CSCO Guidelines. ANNIKO is under regulatory review for nasopharyngeal cancer in the US and China. Clinical studies with ANNIKO are underway for various cancers in China and Australia.[6]

About Nasopharyngeal Carcinoma

Nasopharyngeal carcinoma (NPC) is a malignant tumour with poor survival outcomes. The incidence of NPC is rare in western countries but significantly higher in Southeast Asia. The dramatic geographic difference implies a link between NPC and genetic and/or environmental factors. Indeed, consumption of preserved foods, tobacco smoking, exposure to Epstein Barr virus (EBV) and genetic characteristics have been clearly linked with NPC. However, how these factors lead to NPC remains unclear.[7]

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