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Transcenta Holding Limited

創勝集團醫藥有限公司

(registered by way of continuation in the Cayman Islands with limited liability)

(Stock Code: 6628)

VOLUNTARY ANNOUNCEMENT

BUSINESS UPDATE ON COMPLETION OF ENROLLMENT IN COHORTS C AND G OF CHINA PHASE II CLINICAL STUDY OF OSEMITAMAB (TST001) IN COMBINATION WITH CAPOX WITH OR WITHOUT NIVOLUMAB AS FIRST-LINE TREATMENT OF GASTRIC/GASTRO-ESOPHAGEAL JUNCTION CANCER PATIENTS

This announcement is made by Transcenta Holding Limited (the “**Company**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business update. Capitalized terms used herein but no otherwise defined shall have the same meaning ascribed thereto in the prospectus of the Company dated September 14, 2021.

The board of directors of the Company (the “**Board**”) is pleased to announce that the enrollment of first-line (1L) CLDN18.2 expressing Gastric/Gastro-esophageal Junction (G/GEJ) adenocarcinoma patients in cohorts C and G for the China Phase II study (Transtar-102, NCT04495296) of its high affinity humanized ADCC-enhanced anti-CLDN18.2 monoclonal antibody Osemitamab (TST001) has been completed. Cohort G evaluates Osemitamab (TST001) in combination with Nivolumab plus Capecitabine and Oxaliplatin (CAPOX). Cohort C explores Osemitamab (TST001) in combination with CAPOX. Studies are ongoing in the U.S.

Transtar-102 (NCT04495296) is an ongoing Phase I/II, open-label, multi-cohort, multi-center clinical study in China to evaluate the safety, tolerability and efficacy of Osemitamab (TST001) as single agent or in combination in several different indications. Cohort G evaluates Osemitamab (TST001) at the dose of 3 or 6 mg/kg Q3W in combination with Nivolumab plus CAPOX in 1L non-resectable locally advanced or metastatic G/GEJ adenocarcinoma with various level of CLDN18.2 expression: a total of 82 patients have been enrolled. Preliminary data show the absence of unexpected safety findings; efficacy is immature. Full results from this cohort will be reported in future medical conferences.

Cohort C evaluates Osemitamab (TST001) in combination with CAPOX as 1L treatment of non-resectable locally advanced and metastatic G/GEJ cancer. Enrollment was completed by the end of 2022 and updated efficacy data including duration of response and median progression free survival will be presented in upcoming medical conferences.

These cohorts support the upcoming global Phase III pivotal trial to be initiated in the second half of 2023.

At ESMO 2022, the Company released encouraging interim safety and efficacy data for cohort C including anti-tumor activities in medium and low CLDN18.2 expressing G/GEJ tumors. Osemitamab (TST001) is designed to have higher affinity to bind CLDN18.2 on the tumor cells and enhanced NK cell mediated ADCC activity via fucose reduction. In preclinical models, Osemitamab (TST001) elicits potent in vitro and in vivo anti-tumor activities in CLDN18.2 low expressing gastric cancer tumors.

Gastric cancer (GC) remains the 4th leading cause of cancer death worldwide, accounting for about 7.7% of all cancer related mortality. Combinations of platinum and fluoropyrimidine are the preferred 1L chemotherapy regimen for patients with HER2 negative advanced gastric cancer. Nivolumab was approved in combination with chemotherapy for 1L treatment of patients with advanced or metastatic gastric cancer. Preclinical studies have demonstrated synergistic anti-tumor activities between Osemitamab (TST001) and PD-1 antibody in CLDN18.2 expressing tumor models. Osemitamab (TST001) in combination with Nivolumab plus chemotherapy could become a transformative treatment option for patients with gastric cancer.

“The completion of enrollment of these cohorts marks an important milestone for the Company. These clinical data lay the foundation of our Phase III and comply with dose optimization requirements from Health Authorities. They also provide important information related to the predictive role of CLDN18.2 expression on Osemitamab (TST001) associated outcomes, particularly in the medium and low expressors. We look forward to releasing these data in the very near future.” said Dr. Caroline Germa, the Company’s Executive Vice President, Global Medicine Development and Chief Medical Officer.

INFORMATION ABOUT OSEMITAMAB (TST001)

Osemitamab (TST001) is a high affinity humanized anti-CLDN18.2 monoclonal antibody with enhanced antibody-dependent cellular cytotoxicity (“ADCC”) and complement-dependent cytotoxicity (“CDC”) activities and potent anti-tumor activities in tumor xenograft models. Osemitamab (TST001) is the second most advanced CLDN18.2 targeting antibody being developed globally. Osemitamab (TST001) is generated using the Company’s Immune Tolerance Breaking Technology (IMTB) platform. Osemitamab (TST001) kills CLDN18.2 expressing tumor cells by mechanisms of ADCC and CDC. Leveraging advanced bioprocessing technology, the fucose content of Osemitamab (TST001) was significantly reduced during the production, which further enhanced NK cells mediated ADCC activity of Osemitamab (TST001). Clinical trials for Osemitamab (TST001) are ongoing in the U.S. and China (NCT05190575, NCT04396821, NCT04495296, NCT05608785/CTR20201281). Osemitamab (TST001) was granted Orphan Drug Designation in the U.S. by FDA for the treatment of patients with gastric or gastroesophageal junction (G/GEJ) and pancreatic cancer.

Cautionary statement: We cannot guarantee that we will be able to develop, or ultimately market Osemitamab (TST001) successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
Transcenta Holding Limited
Xueming Qian
Executive Director and Chief Executive Officer

Hong Kong, May 3, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Xueming Qian as executive Director and chief executive officer, Mr. Xiaolu Weng as executive Director, Dr. Yining (Jonathan) Zhao as chairman and non-executive Director, and Mr. Jiasong Tang, Dr. Jun Bao, Mr. Zhihua Zhang and Dr. Kumar Srinivasan as independent non-executive Directors.