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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 THE UNVEILING OF UPDATED EFFICACY DATA FROM OSEMITAMAB (TST001) PLUS CAPOX AS FIRST-LINE TREATMENT FOR G/GEJ CANCER STUDY AT ESMO 2023

Latest data reveals a 55% confirmed response rate, median duration of response (DoR) and median progression-free survival (PFS) of more than 12 months for all patients treated in the expansion cohort

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 excited to announce that it has presented updated efficacy data from the expansion cohort of the TranStar102 of Osemitamab (TST001) plus CAPOX chemotherapy study as the first-line treatment of advanced G/GEJ Cancer at the ESMO Congress 2023 in Madrid, Spain. The updated data continued to show encouraging efficacy from previously disclosed data in patients with CLDN18.2 expression ≥10%, ≥1+ per the LDT assay used to select patients. Two additional posters were presented: one on preclinical data supporting the triple combination of Osemitamab (TST001), nivolumab and chemotherapy over Osemitamab (TST001) and chemotherapy including in PD-L1 negative tumors; and one detailing the clinical pharmacology explorations supporting the recommended Phase III dose.

"These latest datasets further solidify the evidence affirming the efficacy that Osemitamab (TST001) plus CAPOX chemotherapy can provide as a first-line treatment for advanced gastric and gastroesophageal cancer including in tumors with lower levels of CLDN18.2 expression, and provide the rationale to explore the triple combination of Osemitamab (TST001), nivolumab regardless of the PD-L1 CPS levels." said Dr. Caroline Germa, the Company's Executive Vice President, Global Medicine Development and Chief Medical Officer. "We are highly encouraged by the compelling efficacy outcomes from this study in addition to the recent FDA approval to initiate a global Phase III clinical trial, which signifies that Osemitamab (TST001) is poised to redefine the prevailing standard of care for patients with CLDN18.2 positive, HER2 negative gastric and gastroesophageal cancers."

Study Design

Cohort C from Transtar102 study (NCT04495296) was designed to explore the safety and efficacy of Osemitamab (TST001) plus CAPOX as first-line treatment in advanced G/GEJ cancer. In this study, 49 patients were enrolled and treated with 6mg/kg Q3W Osemitamab (TST001) and CAPOX in the efficacy expansion cohort.

Among the 49 patients enrolled, 41 patients had CLDN18.2 positive tumors, and the other 8 patients did not have the biomarker tested. CLDN18.2 expression were tested using the IHC 14G11 LDT assay in a central laboratory. CLDN18.2 positive tumor was defined as ≥ 10% tumor cells staining at least 1+ by the LDT assay, which represents approximately 55% of all the G/GEJ cancer patients.

Encouraging and Durable mDOR and Mpfs

At the cut-off date reported here, the median follow-up for the 49 patients was 11.3 months with the longest treatment duration over 1.5 years. Among the 49 patients, 42 patients had measurable lesions at baseline and at least one post-baseline tumor assessment, and 28 of them achieved partial response, with 23 as confirmed response (54.8%, 23/42). The median duration of response (DoR) of these 23 responders was 12.7 months. 20 patients of the 49 patients had progression of disease or death, with an estimated median progression-free survival (PFS) of 14 months. The median overall survival (OS) was not reached because of the limited number of events, the 12-month survival rate for the overall population of cohort-C (64 patients, all doses) was 88.9% (95% CI: 74.2, 95.4). This further supports the Phase III trial strategy of combining Osemitamab (TST001) with nivolumab and chemotherapy in 1L CLDN18.2 positive G/GEJ cancer which the Company received FDA clearance recently.

Favorable and Manageable Safety Profile

The safety profile of these 49 patients was mainly characterized by manageable on-target-off-tumor effects, including nausea, hypoalbuminemia, and vomiting, most of them were grade 1 or 2 and occurred during the first 2 cycles.

In addition, preclinical data presented at the congress (#1560P) showed significant upregulation of PD-L1 in gastric cancer cells and increased TIL infiltration into tumor upon treatment with Osemitamab (TST001). The combination of anti-CLDN18.2 Osemitamab (TST001) with PD1 inhibitor nivolumab and chemotherapy resulted in significant synergy including in a CLDN18.2 positive/PD-L1 negative PDX model of gastric cancer. 5/8, 2/8, 0/8, 0/8 of the mice treated with Osemitamab (TST001) plus nivolumab and chemotherapy, Osemitamab (TST001) and chemotherapy, nivolumab and chemotherapy or chemotherapy only achieved tumor clearance in the mouse model respectively.

In an ER analysis of data from 58 patients with 1L G/GEJ adenocarcinoma treated with Osemitamab (TST001) and CAPOX, trends of longer PFS/DoR and higher durable ORR were associated with higher Osemitamab (TST001) exposure and was aligned with exposure range achieved by 6 mg/kg Q3W. Safety ER analyses didn't demonstrate clinically significant increase in risk when dose increased from 3 to 6 mg/kg Q3W. Preliminary efficacy, safety and PK/PD data demonstrates favorable benefit risk profile and support future exploration of Osemitamab (TST001) at the dose of 6mg/kg Q3W or 4mg/kg Q2W.

INFORMATION ABOUT OSEMITAMAB (TST001)

Osemitamab (TST001) is a high affinity humanized anti-CLDN18.2 monoclonal antibody with enhanced antibody-dependent cellular cytotoxicity ("**ADCC**"). It has shown potent anti-tumor activities in tumor xenograft models. Osemitamab (TST001) is the second most advanced CLDN18.2 targeting antibody being developed globally. Osemitamab (TST001) was generated using the Company's Immune Tolerance Breaking Technology (IMTB) platform. Osemitamab (TST001) kills CLDN18.2 expressing tumor cells by mechanisms of ADCC. 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, October 23, 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 Zhao as chairman and non-executive Director, and Mr. Jiasong Tang, Mr. Zhihua Zhang, Dr. Kumar Srinivasan and Ms. Helen Wei Chen as independent non-executive Directors.