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 RECEIVAL OF CLEARANCE FROM FDA TO PROCEED WITH GLOBAL PHASE III TRIAL OF OSEMITAMAB (TST001) AS FIRST-LINE TREATMENT FOR GASTRIC/GASTROESOPHAGEAL CANCER PATIENTS

Osemitamab (TST001) on Track to Become a Global Therapy that Elevates the Current Standard of Care for HER2-Negative G/GEJ Adenocarcinoma

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 FDA has granted the Company clearance to proceed with TranStar 301 global Phase III pivotal trial of Osemitamab (TST001) in combination with nivolumab and chemotherapy as first-line treatment in patients with HER2-negative, CLDN18.2 expressing locally advanced or metastatic gastric or gastroesophageal (G/GEJ) adenocarcinoma. This clearance marks a major step forward in the global development of Osemitamab (TST001) and another important milestone following the approvals by the Center for Drug Evaluation (CDE) in China and MFDS in South Korea for the Phase III pivotal trial of Osemitamab (TST001) in July 2023.

This milestone marks a crucial advancement in the progression of Osemitamab (TST001) toward becoming a global therapy that elevates the current standard of care for HER2-negative metastatic gastric or gastroesophageal (G/GEJ) adenocarcinoma. By specifically targeting CLDN18.2 and combining it with nivolumab and chemotherapy, Osemitamab (TST001) is poised to reshape the treatment paradigm for G/GEJ cancer.

Stomach cancer remains an important cancer worldwide and is responsible for over one million new cases in 2020 and an estimated 769,000 deaths (equating to one in every 13 deaths globally), ranking fifth for incidence and fourth for mortality globally[1]. Combinations of platinum and fluoropyrimidine represent the backbone chemotherapy regimen for patients with HER2-negative advanced gastric cancer[2]. Nivolumab was approved in combination with chemotherapy for first-line treatment of patients with advanced or metastatic gastric cancer. Though treatment outcomes have improved, the median overall survival of nivolumab plus chemotherapy is still less than 14 months[3].

Osemitamab (TST001) is a second-generation humanized CLDN18.2 targeting antibody with improved CLDN18.2 binding affinity and enhanced antibody-dependent cellular cytotoxicity ("**ADCC**"). It has shown anti-tumor activities in preclinical tumor models with a broad range of CLDN18.2 expression.

To support the global Phase III trial application and FDA EOP2 meeting, the Company has conducted Phase II clinical trials in both the U.S. and China of the combination of Osemitamab (TST001) with chemotherapy or nivolumab and chemotherapy with multiple Osemitamab (TST001) doses cohorts to optimize the dose for the global Phase III trial. Furthermore, the Company has developed a CLDN18.2 specific companion diagnostic assay with a credible CDx developer in the U.S.

At the 2023 ASCO annual meeting and 2023 ESMO GI conference, the Company presented encouraging efficacy data of Osemitamab (TST001) in combination with CAPOX as the first-line treatment of G/GEJ cancer. A total of 64 patients were enrolled and treated with Osemitamab (TST001) at doses ranging between 1 and 8mg/kg Q3W in a dose escalation and dose expansion cohort. CLDN18.2 positivity (defined as: IHC membrane staining ≥10% tumor cells with ≥1+ intensity per LDT assay, selecting approximately 55% of the screened patients) was required for the efficacy expansion. The data showed that the estimated median progression-free survival (PFS) was 9.5 months for all dose groups, consistent across all CLDN18.2 expression levels, with a median duration of response (DOR) of 9.9 months. PFS and DOR data for the 49 patients treated at the dose of 6mg/kg Q3W in the efficacy expansion will be presented at ESMO 2023. These data also show that the CLDN18.2 positive patients benefiting from the addition of Osemitamab (TST001) to standard of care could represent more than 55% of all G/GEJ adenocarcinomas.

"We are delighted with the positive outcome of the EOP2 meeting," said Dr. Caroline Germa, the Company's Executive Vice President, Global Medicine Development and Chief Medical Officer. "The interim safety, clinical pharmacology and efficacy data we presented fostered a productive dialogue with the FDA. Securing FDA endorsement on critical program elements represents a pivotal milestone in advancing our Phase III trial in the U.S.".

References:

[1] Hyuna Sung, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA CANCER J CLIN 2021;71:209-249

[2] NCCN guideline for Gastric Cancer Version 2.2022

[3] Janjigian YY, Shitara K, Moehler M, et al. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. Lancet 2021;398:27-40

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 4, 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.