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 APPROVALS FROM CHINA CDE AND SOUTH KOREA MFDS TO INITIATE TRANSTAR 301 GLOBAL PHASE III PIVOTAL TRIAL OF OSEMITAMAB (TST001)

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 the Company has received approvals from China CDE (Center for Drug Evaluation) and South Korea MFDS (Ministry of Food and Drug Safety) to initiate TranStar 301 global Phase III pivotal trial of Osemitamab (TST001) in combination with Nivolumab and chemotherapy for the first-line treatment of patients with HER2 negative, CLDN18.2 expressing locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. In addition, we are in the process of EU and FDA regulatory interaction.

Gastric cancer (GC) is the 4th leading cause of cancer death worldwide, accounting for about 7.7% of all cancer related mortality. The five year survival rate for gastric cancer is still around 30%. Nivolumab, an anti-PD-1 antibody, has been approved globally for the first-line treatment of patients with advanced or metastatic HER2-negative G/GEJ adenocarcinoma cancer.

Osemitamab (TST001) is a second generation humanized CLDN18.2 targeting antibody with enhanced ADCC. It has shown anti-tumor activities in preclinical models with a broad range of CLDN18.2 expression. Recently, the Company presented efficacy data of Osemitamab (TST001) in combination with CAPOX as the first-line treatment of G/GEJ adenocarcinoma cancer at 2023 ASCO annual meeting and 2023 ESMO GI. Among 64 patients with CLDN18.2 positive (defined as: IHC membrane staining ≥10% tumor cells with ≥1+ intensity per LDT assay, selecting approximately 55% of the screened patients) were treated, 49 at the dose of 6mg/kg. The data showed that the estimated median progression-free survival was 9.5 months from all dose groups, consistent across all CLDN18.2 expression levels, with a median duration of response of 9.9 months.

Preclinical studies have demonstrated synergistic anti-tumor activities between Osemitamab (TST001) and anti-PD-1 antibodies in CLDN18.2 expressing tumor models. Recently, the Company has reported that 82 patients had been enrolled in TranStar 102 to assess the safety and efficacy of Osemitamab (TST001) in combination with Nivolumab and CAPOX. So far, the combination is well tolerated.

TranStar301 is a global randomized, double-blind, placebo-controlled Phase III trial designed to evaluate Osemitamab (TST001) in combination with Nivolumab plus chemotherapy as the first-line treatment for patients with locally advanced or metastatic HER2 negative, CLDN18.2 expressing G/GEJ adenocarcinoma.

"We are actively progressing our plans to develop Osemitamab (TST001) in combination with Nivolumab and chemotherapy as first-line treatment for CLDN18.2 expressing G/GEJ adenocarcinomas in a large multinational Phase III clinical trial. CDE and MFDS approvals are exciting milestones, with several others coming soon. We are looking forward to sharing more information as it becomes available." said Dr. Caroline Germa, the Company's Executive Vice President, Global Medicine Development and Chief Medical Officer.

References:

[1] 2023 ESMO Poster: https://www.transcenta.com/Scientific_Publications/id-125.html
[2] 2023 ASCO Poster: https://www.transcenta.com/Scientific_Publications/id-124.html

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 Transcenta'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, July 7, 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.