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 FIRST PATIENT DOSED IN THE PHASE IIA STUDY OF CLAUDIN18.2 MONOCLONAL ANTIBODY TST001 COMBINED WITH CISPLATIN AND GEMCITABINE FOR THE FIRST LINE TREATMENT OF BILIARY TRACT CANCER

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 the successful dosing of the first patient in China Phase IIa Study of TST001, a Claudin18.2 monoclonal antibody, combined with Cisplatin and Gemcitabine for the first line treatment of systemic treatment-naïve locally advanced or metastatic biliary tract cancer patients. Globally the Company is the first company exploring the potential of Claudin 18.2 targeting agent in biliary tract cancer.

Biliary tract cancer is a relatively rare malignancy, which includes cholangiocarcinoma and gallbladder carcinoma. Cholangiocarcinoma is further classified into extrahepatic and intrahepatic cholangiocarcinoma. In the treatment of biliary tract cancer, radical resection is the standard and only approach for patients at the early stage. However, most of the patients cannot receive surgical resection, as the cancer has stepped into the metastatic stage by the time of diagnosis. For biliary tract cancer, few effective therapies are available for these patients, which leaves significant unmet clinical needs.

This Phase IIa clinical trial is an open-label, single-arm, multi-center study designed to evaluate the safety, tolerability, and anti-tumor efficacy of TST001 in patients with systemic treatment-naïve locally advanced or metastatic biliary tract cancer. These patients will be screened using an immunohistochemistry detection assay developed by the Company and validated by central lab that specifically detects Claudin18.2 but not Claudin 18.1.

"Biliary tract cancer has poor prognosis and the combination of Cisplatin and Gemcitabine is the standard of care for first line treatment." said Dr. Michael Shi, EVP, our Head of Global R&D and CMO. "Using our proprietary IHC antibody, we have shown that Claudin 18.2 is over-expressed in the tumor of a subset of biliary tract cancer patients. As the combination of Claudin18.2 targeting agent with chemo backbone has shown promising activity in first line gastric cancer, the addition of TST001 to the first line chemotherapy regimen may also provide better treatment benefit to biliary tract cancer patients with Claudin18.2-expressing tumor."

INFORMATION ABOUT TST001

TST001 is a high affinity humanized anti-Claudin18.2 monoclonal antibody with enhanced antibody-dependent cellular cytotoxicity ("**ADCC**") and complement-dependent cytotoxicity ("**CDC**") activities and potent anti-tumor activities in tumor xenograft models. TST001 is the second Claudin18.2 targeting antibody therapeutic candidate being developed globally. TST001 is generated using the Company's Immune Tolerance Breaking Technology (IMTB) platform. TST001 kills Claudin18.2 expressing tumor cells by mechanisms of ADCC and CDC. Leveraging advanced bioprocessing technology, the fucose content of TST001 was significantly reduced during the production, which further enhanced NK cells mediated ADCC activity of TST001. Clinical trials for TST001 are ongoing in China and US (NCT04396821, NCT04495296/CTR20201281). TST001 was granted Orphan Drug Designation in the US by FDA for the treatment of patients with gastric cancer or gastroesophageal junction (GC/GEJ).

Cautionary statement: We cannot guarantee that we will be able to develop, or ultimately market, 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, February 28, 2022

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, Dr. Michael Ming Shi and Mr. Albert Da Zhu as executive Directors, Dr. Yining (Jonathan) Zhao as chairman and non-executive Director, and Mr. Jiasong Tang, Dr. Jun Bao and Mr. Zhihua Zhang as independent non-executive Directors.