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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 PUBLICATION OF PRECLINICAL RESULTS OF [¹⁷⁷Lu]Lu-TST001 RADIONUCLIDE ANTIBODY CONJUGATE AS POTENTIAL NOVEL TREATMENT OPTION FOR METASTATIC GASTRIC CANCER IN THE EUROPEAN JOURNAL OF NUCLEAR MEDICINE AND MOLECULAR IMAGING (EJNMMI)

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 preclinical anti-tumor efficacy and safety results of [¹⁷⁷Lu]Lu-TST001 have been published on European Journal of Nuclear Medicine and Molecular Imaging (EJNMMI). In this preclinical studies, [¹⁷⁷Lu] Lu-TST001 demonstrated significant antitumor efficacy with acceptable toxicity. It exhibits strong potential for clinical translation, providing a new promising treatment option for CLDN18.2-overexpressing tumors, including gastric cancer.

This research was conducted in collaboration between the Company and the team of Professor Hua Zhu from Beijing Cancer Hospital. In this study, a [¹⁷⁷Lu]Lu-TST001 radionuclide antibody conjugate was developed that targets CLDN18.2 using a DOTA-TST001 as a precursor and is labeled with ¹⁷⁷Lu, a therapeutic radionuclide. The clear molecular imaging, favorable biodistribution, and pharmacokinetics of [¹⁷⁷Lu]Lu-TST001 were validated in a mouse xenograft GC model. Moreover, this study explored the short-term therapeutic efficacy of [¹⁷⁷Lu]Lu-TST001 radioimmunotherapy (RIT) against CLDN18.2-positive tumors and determined the optimal therapeutic dose in a GC tumor model. Safety under the treatment dose of the probe was also examined. Significant therapeutic effects with acceptable short-term toxicity were achieved in the mouse model.

“The study represents the first application of the therapeutic radionuclide [¹⁷⁷Lu]Lu-labeled CLDN18.2-targeting antibody TST001. This radionuclide antibody conjugate demonstrates great potential as an RIT drug for clinical application, which may offer a promising new treatment option for CLDN18.2-overexpressing tumors, such as gastric cancer, pancreatic cancer, esophageal cancer, and lung cancer, leading to improved survival outcomes.” said Professor Hua Zhu from Beijing Cancer Hospital.

“Compared to localized gastric cancer, advanced metastatic gastric cancer often cannot be cured by chemotherapy or external radiation alone. In such cases, targeted RIT provides an opportunity to deliver radiation selectively to disease sites in patients with metastases, regardless of disease stage, offering a potential clinical treatment strategy for advanced tumor patients. We look forward to continuing our work with Professor Hua Zhu and his team in an effort to bring [¹⁷⁷Lu]Lu-TST001 radionuclide antibody conjugate to patients in the near future.” said Dr. Xueming Qian, CEO of the Company.

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, December 13, 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.