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 APPROVAL FROM CHINA CDE FOR THE COMPANY'S ANTI-SCLEROSTIN MONOCLONAL ANTIBODY TST002 (BLOSOZUMAB) TO INITIATE PHASE II CLINICAL TRIAL IN PATIENTS WITH REDUCED BONE MINERAL DENSITY

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 received approval from China Center for Drug Evaluation (CDE) to initiate Phase II clinical trial of TST002 (Blosozumab). This study aims to evaluate the safety, tolerability, and pharmacokinetics of TST002 (Blosozumab) after single and multiple intravenous administrations in patients with reduced bone mineral density.

Osteoporosis is a significant health concern for the middle-aged and elderly population in China. It is estimated that by 2050, the number of osteoporosis patients will reach 120 million. Compared with RANKL mAbs, sclerostin mAbs successfully achieve the dual goal of preventing bone loss and rebuilding the bone. Eventity (Romosozumab) of Amgen is the only anti-sclerostin antibody drug that has been approved by the FDA in the United States. Up to the present, there was no anti-sclerostin antibody drug approved in China.

In May 2023, the Company presented Phase I unblinded data, which showed that the overall safety and tolerability of TST002 (Blosozumab) in all dose cohorts is favorable. On the efficacy side, all dose cohorts from 200-1,200 mg have shown a clinically meaningful increase in lumbar spine BMD on day 85 (D85) after single dose of TST002 (Blosozumab) and comparable to those of Blosozumab single dose study at the similar dose levels. The average increase of lumbar spine BMD at day 85 (D85) from baseline ranged from 3.52% to 6.20% across dose cohorts, all exceeding the least significant difference (2.77%). The increase of lumbar spine BMD in the placebo group was only 0.30% even with optimal calcium and vitamin D supplemental treatment. In addition, encouraging BMD increase in total hip from 1.30% to 2.24% across dose cohorts were observed after single dose of TST002 (Blosozumab). In comparison, the mean percent change in lumbar spine BMD from baseline to month 12 was 5.4% after one year of denosumab treatment.[1]

"We are excited to have received the clearance to move forward from CDE. Our Phase II will assess several regimens of TST002 (Blosozumab) with reduced dosing frequency, bringing us closer to our Phase III. We look forward to fully exploring the differentiated profile of TST002 (Blosozumab) to address the unmet medical need of the large patient population who suffers from osteoporosis." said Dr. Caroline Germa, the Company's Executive Vice President, Global Medicine Development and Chief Medical Officer.

Reference:

[1] https://academic.oup.com/jcem/article/105/3/e255/5607536

INFORMATION ABOUT TST002 (BLOSOZUMAB)

TST002 (Blosozumab) is a humanized anti-sclerostin monoclonal antibody as a drug candidate for osteoporosis and other bone loss diseases. It has a dual effect possessing both anabolic and anti-resorptive effects, which stimulates bone formation and inhibits bone absorption, resulting in fast increase in bone mineral density and bone strength. Blocking sclerostin activity in human treated with anti-sclerostin antibody or with naturally occurring genetic deletion has been shown to be an effective approach in increasing bone mineral density (BMD) and reducing bone fracture. Currently there is no approved anti-sclerostin antibody therapy in China yet although Romosozumab from Amgen has been approved in the United States, Europe and Japan.

Cautionary statement: We cannot guarantee that we will be able to develop, or ultimately market TST002 (Blosozumab) 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 31, 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, Dr. Jun Bao, Mr. Zhihua Zhang and Dr. Kumar Srinivasan as independent non-executive Directors.