Cutia Therapeutics
科笛集团
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

COMPLETION OF PHASE I CLINICAL TRIAL OF CU-20401 (RECOMBINANT MUTANT COLLAGENASE) FOR ABDOMINAL ADIPOSE ACCUMULATION IN CHINA

This announcement is made by Cutia Therapeutics (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

The board of directors (the "**Board**") of the Company is pleased to announce that the Group has completed a Phase I clinical trial of CU-20401 (recombinant mutant collagenase), a potential Class I new drug, for abdominal adipose accumulation. A total of 48 patients received CU-20401 treatment for abdominal adipose accumulation in this Phase I clinical trial in China. This clinical trial was a single-center, open label, placebo-controlled and dose escalation trial to evaluate the safety and tolerability of CU-20401.

Data from the clinical trial demonstrated an overall favorable safety and tolerability profile for CU-20401, with no significant dose-related effects. There were no Grade 3 or above treatment-emergent adverse events ("**TEAE**") and treatment-related adverse events ("**TRAE**"), serious adverse events (SAE), or TEAEs and TRAEs leading to withdrawal from the clinical trial in all dosage groups. In addition, plasma drug concentration in all enrolled patients were below the lower limit of detection, indicating the systemic exposure after subcutaneous injection of CU-20401 was extremely low.

Data from the clinical trial also showed preliminary efficacy trends. The reduction of subcutaneous fat volume relative to baseline was more pronounced in the abdominal treatment area of the enrolled patients during the three-month follow up period as duration prolonged.

CU-20401 is a recombinant mutant collagenase that targets obesity, overweight, or other localized adipose accumulation associated metabolic diseases. CU-20401 adopts an alternative mechanism of action where it acts as a collagenase to selectively act on the extracellular matrix attached to adipose tissue. After localized injection, CU-20401 degrades extracellular matrix collagen in the subcutaneous fat layer which leads to apoptosis of adipocytes, and is expected to effectively reduce localized adipose accumulation. CU-20401 is technologically modified with reduced rate to catalyze the collagen degradation with mild catalytic activity, thus reducing the adverse effects of wild-type collagenase, such as bruising and pain.

Warning: There is no assurance that CU-20401 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Cutia Therapeutics
Zhang Lele
Chief Executive Officer and Executive Director

Hong Kong, 28 February 2024

As at the date of this announcement, the Board comprises (i) Ms. Zhang Lele and Mr. Huang Yuqing as executive directors; (ii) Dr. Chen Lian Yong, Dr. Xie Qin, Dr. Huang Xiao and Ms. Yang Yunxia as non-executive directors; and (iii) Mr. Chung Ming Kit, Mr. Tao Tak Yan Dennis and Mr. Ye Xiaoxiang as independent non-executive directors.