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

VOLUNTARY ANNOUNCEMENT

PHASE II CLINICAL TRIAL OF CU-20401 (RECOMBINANT MUTANT COLLAGENASE) FOR SUBMENTAL ADIPOSE ACCUMULATION REACHED PRIMARY ENDPOINT

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 Phase II clinical trial (the "**Clinical Trial**") of CU-20401 (recombinant mutant collagenase), a potential Class I new drug of the Group, for the treatment of submental adipose accumulation in China, has obtained top-line results. Results indicated that the Clinical Trial has reached its primary endpoint with statistically significant and clinically meaningful outcomes.

The Clinical Trial is a multi-center, randomized, double-blind and placebo-controlled trial to evaluate the efficacy and safety of CU-20401 for the treatment of moderate to severe submental adipose accumulation, with a total of 108 subjects enrolled.

Result analysis showed that:

- In terms of efficacy, primary efficacy endpoint results demonstrated that the treatment efficacy of both the low dosage and high dosage groups of CU-20401 were superior to that of the placebo-controlled group, with statistically significant differences in efficacy. Secondary efficacy endpoint results also demonstrated similar efficacy advantage.

- In terms of safety, there were no adverse events including those Grade ≥3 events as defined by the Common Terminology Criteria for Adverse Events (CTCAE), events that led to drug adjustments, withdrawal from the clinical trial or serious adverse events (SAEs) in the CU-20401 groups (including low dosage and high dosage groups) during the entire clinical trial period.

- Overall, CU-20401 demonstrated significant and robust efficacy advantages with favorable safety profile.

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 acts 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, 29 November 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.