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

VOLUNTARY ANNOUNCEMENT

COMPLETION OF PHASE II CLINICAL TRIAL OF CU-20401 (RECOMBINANT MUTANT COLLAGENASE) FOR SUBMENTAL 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 the Phase II clinical trial (the "**Clinical Trial**") of CU-20401 (recombinant mutant collagenase), a potential Class I new drug of the Group, for submental adipose accumulation in China. The Clinical Trial has demonstrated significant and robust efficacy advantages with favorable safety profile.

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. A total of 108 subjects were enrolled and randomly assigned in a 1:1:1 ratio to three groups, including the CU-20401 low-dose group (the "**Low-Dose Group**"), the CU-20401 high-dose group (the "**High-Dose Group**"), and the placebo-controlled group (the "**Placebo Group**"). All three groups received single administration, and treatment compliance among the subjects was 100%.

Results of the Phase II Clinical Ttrial

Efficacy Results

- The primary efficacy endpoint results demonstrated that the treatment efficacy of both the High-Dose Group and the Low-Dose Group were superior to that of the Placebo Group, with statistically significant differences in efficacy. Secondary efficacy endpoint results also demonstrated similar efficacy advantage.

- As the follow-up period extended, the treatment efficacy of both the High-Dose Group and the Low-Dose Group showed more significant improvement compared to baseline, and the treatment benefits were also greater than those of the Placebo Group.

- Preliminary observations from the Clinical Trial indicated that the High-Dose Group had greater efficacy advantage compared to the Placebo Group, showing a dose-response trend.

Safety Results

- 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 both the High-Dose Group and the Low-Dose Group during the entire clinical trial period.

- The overall safety profile of CU-20401 was favorable. The distribution of incidence rate and severity level of adverse events was similar between the High-Dose Group and the Low-Dose Group, with no observed dosage-related differences in the incidence rate and severity level of adverse events.

About CU-20401

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.

In January 2024 and June 2024, the Group announced the enrollment of the first and the last subject in the Clinical Trial, respectively. In November 2024, the Group announced that the Clinical Trial had reached its primary endpoint.

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, 31 December 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.