Cutia Therapeutics

科笛集团

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

PHASE I CLINICAL TRIAL OF CU-40101 (TOPICAL SMALL MOLECULE THYROID HORMONE RECEPTOR AGONIST LINIMENT) IN CHINA 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 I clinical trial of the Group's CU-40101 (topical small molecule thyroid hormone receptor agonist liniment) conducted in China for the treatment of androgenetic alopecia reached primary endpoint. The Phase I clinical trial of CU-40101 was a randomized, double-blind, placebo-controlled and dose-escalation trial to evaluate the safety, tolerability and pharmacokinetic (PK) features of CU-40101 in Chinese adult male patients with androgenetic alopecia.

The Phase I clinical trial of CU-40101 in China was divided into single-dose administration and multiple-dose administration, each of which enrolled 40 Chinese adult male patients with androgenetic alopecia. For the single-dose administration, 30 enrolled patients were randomly allocated to the CU-40101 group, and 10 enrolled patients were allocated to the placebo group, who were administered only in the morning of the first day during the treatment. For the multiple-dose administration, 32 enrolled patients were randomly allocated to the CU-40101 group, and 8 enrolled patients were allocated to the placebo group, who were administered in the morning of every day during the ten-day treatment and administered once every 24 hours.

The results of this clinical trial showed a good safety profile of CU-40101, with no enrolled patients experiencing local tolerability problems after single-dose and multiple-dose administration, thus reaching the primary endpoint. In terms of safety, there were no serious adverse events (SAE), treatment-emergent adverse events (TEAE) of Grade 3 or above under the common terminology criteria for adverse events (CTCAE), deaths or major adverse events. In addition, no clinically meaningful results of thyroid function abnormalities and thyroid ultrasound abnormalities were reported, further demonstrating the favorable safety profile of CU-40101. In terms of tolerability, no enrolled patients experienced adverse events (AE) related to local skin tolerance assessment, indicating that the enrolled patients had good local tolerance to the administration area.

In addition, the PK study showed that drug concentration was not detected in most of the enrolled patients, indicating the drug's systemic exposure after skin administration was extremely low.

CU-40101 contains a potent small molecule thyroid hormone receptor agonist that binds to thyroid receptor in hair follicle cells and induces hair growth. CU-40101 is to be applied to the scalp directly, reducing systemic exposure to the drug and the associated adverse effects. CU-40101 is differentiated from currently available androgenetic alopecia treatment in its mechanism of action and the potential to be used in both male and female patients.

Warning: There is no assurance that CU-40101 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, 2 November 2023

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, 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.