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

VOLUNTARY ANNOUNCEMENT

RESULTS OF PHASE III CLINICAL TRIALS OF CU-40102 (TOPICAL FINASTERIDE SPRAY) AND CU-10201 (TOPICAL 4% MINOCYCLINE FOAM) IN THE PRC PUBLISHED AT THE 18TH CDA ANNUAL MEETING

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 results of the Phase III clinical trials of the Group's CU-40102 (topical finasteride spray) for the treatment of androgenetic alopecia and CU-10201 (topical 4% minocycline foam) for the treatment of non-nodular moderate to severe acne vulgaris in the People's Republic of China (the "**PRC**") were published at the 18th Annual Meeting of China Dermatologist Association & National Congress of Cosmetic Dermatology (the "**18th CDA Annual Meeting**").

Results of the registrational Phase III clinical trial of CU-40102 (topical finasteride spray) in the PRC

CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and currently the only topical finasteride under clinical development in the PRC. The registrational Phase III clinical trial of CU-40102 in the PRC was a multi-center, randomized, double-blind, and placebo-controlled trial to evaluate the efficacy and safety of CU-40102 in Chinese male adult patients with androgenetic alopecia. A total of 270 Chinese male adult patients with androgenetic alopecia were enrolled in the clinical trial. During the 24-week continuous treatment period, enrolled patients were topically administered with CU-40102 on the local scalp area once a day.

Results of the clinical trial showed that, in terms of efficacy, improvement of the total hair count and terminal hair count in the targeted bald area of the CU-40102 group was significantly better than that of the placebo group after 24 weeks of treatment. The difference was statistically significant (P<0.05), reached primary endpoint and key secondary endpoint, and efficacy began to show from week 12.

Additionally, based on the investigator assessment score of the targeted bald area, efficacy shown in the CU-40102 group was significantly better than that shown in the placebo group after 24 weeks of treatment, and the difference was statistically significant (P<0.05).

In terms of safety, enrolled patients of the CU-40102 group showed favourable local tolerance to the administration area, and the overall incidence of adverse events in the CU-40102 group was similar to that of the placebo group. There were no treatment-emergent serious adverse events ("**TESAEs**"), or treatment-emergent adverse events ("**TEAEs**") leading to death.

Meanwhile, a Phase I pharmacokinetic study of CU-40102 in Chinese male adult patients with androgenetic alopecia conducted in the same period showed that after the administration of finasteride spray, systemic absorption was minimal in the group of Chinese androgenetic alopecia patients.

The registrational Phase III clinical trial of CU-40102 in the PRC has reached primary endpoint. For more information, please refer to the voluntary announcement of the Company dated 7 September 2023.

Results of the registrational Phase III clinical trial of CU-10201 (topical 4% minocycline foam) in the PRC

CU-10201 is the first and only topical minocycline approved for acne vulgaris treatment globally and the first topical minocycline to have its New Drug Application (the "**NDA**") accepted by the National Medical Products Administration (the "**NMPA**") of the PRC. The registrational Phase III clinical trial of CU-10201 in the PRC was a multi-center, randomized, double-blind, and placebo-controlled trial to evaluate the efficacy and safety of patients aged nine years old or above with moderate to severe acne vulgaris. A total of 372 patients aged nine years old or above with moderate to severe acne vulgaris were enrolled in the clinical trial. During the 12-week continuous treatment period, enrolled patients were topically administered with CU-10201 on the acne site once a day.

Results of the clinical trial showed that, in terms of efficacy, improvement in the inflammatory skin lesion of the CU-10201 group was significantly better than that of the placebo group after 12 weeks of treatment. The difference was statistically significant (P<0.001), reached primary endpoint and the difference in efficacy better than placebo group began to show after week four. Efficacy shown in the CU-10201 group gradually increased during the administration period.

Additionally, based on the the successful rate of the Investigator Global Assessment (IGA) score, improvement in the non-inflammatory skin lesion of the CU-10201 group was significantly better than that of the placebo group after 12 weeks of treatment. The difference was statistically significant (P<0.05) and reached secondary endpoint.

In terms of safety, enrolled patients of the CU-10201 group showed favourable local tolerance to the administration area, and the overall incidence of adverse events in the CU-10201 group was similar to that of the placebo group. There were no TESAEs related to the drug, TEAEs leading to death, or TESAEs leading to discontinuation of the drug or withdrawal from the trial.

CU-10201 has been granted priority review designation by the Center for Drug Evaluation of the NMPA and its NDA has also been accepted by the NMPA. For more information, please refer to the voluntary announcements of the Company dated 10 August 2023 and 27 September 2023, respectively.

Warning: There is no assurance that CU-40102 and CU-10201 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, 11 December 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 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.