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

VOLUNTARY ANNOUNCEMENT

RESULTS OF PHASE III CLINICAL TRIAL OF CU-40102 (TOPICAL FINASTERIDE SPRAY) AND CU-30101 (LOCALIZED TOPICAL LIDOCAINE AND TETRACAINE CREAM) IN CHINA WERE PRESENTED AT THE 19TH 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 trial in China of the Group's products, CU-40102 (topical finasteride spray) for the treatment of androgenetic alopecia and CU-30101 (localized topical lidocaine and tetracaine cream) for surface dermatologic operations, were presented through electronic posters at the 19th Annual Meeting of China Dermatologist Association & National Congress of Cosmetic Dermatology (the "**CDA Annual Meeting**"). The Group's research results have been selected for the CDA Annual Meeting for two consecutive years, representing the Group's influence in the industry and its advanced standing in the field of dermatology.

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

The registrational Phase III clinical trial of CU-40102 in China 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 subjects were enrolled, with the primary efficacy endpoint being the change in total hair count within the targeted bald area at the vertex from baseline in week 24. Adverse events and local skin tolerability were also being assessed.

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 subjects in the CU-40102 group was significantly better than that of the placebo group after 24 weeks of treatment. The differences were 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 subjects of the CU-40102 group showed favorable 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.

The New Drug Application (the "**NDA**") for CU-40102 was accepted by the National Medical Products Administration (the "**NMPA**") of China in January 2024. The Group also submitted an NDA to the Department of Health in Hong Kong, China in April 2024. For more information, please refer to the voluntary announcements of the Company dated 31 January 2024 and 30 April 2024.

Results of the registrational Phase III clinical trial of CU-30101 (localized topical lidocaine and tetracaine cream) in China

The registrational Phase III clinical trial of CU-30101 in China was a multi-center, randomized, double-blind, positive drug control and pairing designed trial to evaluate the safety and efficacy of CU-30101 for localized analgesia in surface dermatologic operations. A total of 286 subjects were enrolled, Pliaglis® lidocaine and tetracaine cream ("**Pliaglis®**") served as the control drug and the reference product, with the primary efficacy endpoint being Visual Analog Scale ("**VAS**") for immediate pain assessment after fractional laser surgery. Adverse events and local skin tolerability were also being assessed.

Results of the clinical trial showed that, in terms of efficacy, VAS differences (CU-30101 side-Pliaglis® side) on both sides of the face were within the preset equivalence interval, and CU-30101 was as effective as Pliaglis® in analgesia and achieved the primary endpoint. In addition, no statistical differences were observed (P >0.05) in the differences in the evaluation of "whether the two studied drugs provide the enrolled subjects with adequate pain relief", "whether the studied drugs will be used again for localized dermatologic anesthesia" and "investigator satisfaction on the effectiveness of the two studied drugs". In terms of safety, the clinical trial demonstrated an overall favorable safety profile for CU-30101, with no severe adverse events or serious adverse events. The assessment of local tolerance on the CU-30101 side was similar to that on the Pliaglis® side and was consistent with the known safety profile of Pliaglis®, with no new safety signals observed.

Drug marketing authorization application for CU-30101 was accepted by the NMPA in July 2024. For more information, please refer to the voluntary announcement of the Company dated 31 July 2024.

Warning: There is no assurance that CU-40102 and CU-30101 will ultimately be successfully 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 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.