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-10201 (TOPICAL 4% MINOCYCLINE FOAM) IN THE PRC PUBLISHED ONLINE IN THE JOURNAL OF THE EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

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 of the Group's 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 online in the *Journal of the European Academy of Dermatology and Venereology* (JEADV), the official publication of the European Academy of Dermatology and Venereology (EADV).

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 CU-10201 in patients aged nine years old or above with moderate to severe acne vulgaris.

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 ($P<0.001$) and reached primary endpoint. Additionally, based on 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 treatment-emergent serious adverse events (TESAEs) related to the drug.

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-10201 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, 30 July 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.