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Cutia Therapeutics

科笛集团

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

NEW DRUG APPLICATION FOR CU-10201 (TOPICAL 4% MINOCYCLINE FOAM) ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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.

Reference is made to the voluntary announcement of the Company dated 10 August 2023 in relation to CU-10201 (topical 4% minocycline foam) having been granted priority review designation by the Center for Drug Evaluation of the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China (the “**PRC**”).

The board of directors (the “**Board**”) of the Company is pleased to announce that the New Drug Application (the “**NDA**”) for CU-10201 was accepted by the NMPA of the PRC. The indication of CU-10201 is for the treatment of non-nodular moderate to severe acne vulgaris in pediatric and adult patients aged nine years and older.

CU-10201 is the first and only topical minocycline approved for acne vulgaris treatment globally and the first topical minocycline to have its NDA accepted by the NMPA of the PRC. Minocycline is a tetracycline antibiotic used to treat a number of bacterial infections and acne vulgaris. The currently available minocycline products are mostly oral medications. Compared to other major anti-acne antibiotics and conventional oral drugs, topical minocycline foam has lower systemic drug exposure, fewer side effects, a lower rate of drug resistance and likely higher patient compliance.

Results of Phase III clinical trial data analysis in the PRC showed that CU-10201 has a significant efficacy and a favorable safety profile in the treatment of acne, with a reduction in the common side effects of oral minocycline.

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, 27 September 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.