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Cutia Therapeutics

科笛集团

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

CU-30101 (LOCALIZED TOPICAL LIDOCAINE AND TETRACAINE CREAM) OBTAINED DRUG MARKETING AUTHORIZATION BY THE NMPA

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 CU-30101 (localized topical lidocaine and tetracaine cream) of the Group has obtained drug marketing authorization by the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China (“**China**”).

CU-30101 is a localized lidocaine and tetracaine compound topical anesthesia cream for topical anesthesia operations. The formulation of lidocaine and tetracaine combination in CU-30101 may produce rapid and long-lasting anesthetic effects due to its ingredients’ unique pharmacokinetic properties. Lidocaine diffuses more rapidly, and more extensively than tetracaine, whereas tetracaine, a long-acting localized anesthetic amino acid ester, is more lipophilic than lidocaine and can be concentrated in the topical stratum corneum. The localized topical cream formulation also limits systemic absorption of the anesthetic component ingredients, thereby providing a favorable safety profile.

The drug marketing authorization of CU-30101 is based on the results of its Phase III clinical trial (the “**Clinical Trial**”) completed in China. The Clinical Trial demonstrated that CU-30101 was as effective as its control drug and reference product, Pliaglis® lidocaine and tetracaine cream (“**Pliaglis®**”), in analgesia and demonstrated an overall favorable safety profile. The local tolerance assessment of CU-30101 was similar to that of Pliaglis®, and was consistent with the known safety profile of Pliaglis®, with no new safety signals observed.

As the Group's first product approved by the NMPA in the topical anesthesia sector and the Group's third approved product following CU-10201 (topical 4% minocycline foam) and CU-40102 (topical finasteride spray), CU-30101 will facilitate the expansion of the Group's sales channel and the commercialization of subsequent products. Thereby, CU-30101 will further strengthen the Group's commercial footprint in the broader dermatology treatment and care market.

Warning: There is no assurance that 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, 7 May 2026

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, Mr. Lu Minfang and Ms. Yang Yunxia as non-executive directors; and (iii) Mr. Chung Ming Kit, Mr. Zhang Zhisong and Mr. Ye Xiaoxiang as independent non-executive directors.