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Cutia Therapeutics

科笛集团

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

CU-20101 (BOTULINUM TOXIN TYPE A FOR INJECTION) FOR IMPROVING MODERATE TO SEVERE GLABELLAR LINES ACHIEVED POSITIVE TOPLINE RESULTS FROM PHASE III CLINICAL TRIAL IN CHINA

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 the Group’s CU-20101 (botulinum toxin type A for injection) for improving moderate to severe glabellar lines has achieved positive topline results from a Phase III clinical trial in China (the “**Clinical Trial**”).

This Clinical Trial is a two-phase study. Phase one is a randomized, multi-center, double-blind, positive drug control clinical trial. Phase two is an open-label clinical trial designed to evaluate the efficacy and safety of CU-20101. BOTOX® botulinum toxin type A for injection (“**BOTOX®**”) served as the control and the reference product for this Clinical Trial. All enrolled subjects have completed the Clinical Trial in November 2025 and database lock was completed in early January 2026.

Results of the Clinical trial showed that, in terms of efficacy using the Facial Wrinkle Scale (FWS), the success rate of glabellar lines treatment based on on-site investigator’s assessment and participant evaluation met the non-inferiority standard, and the success rate of the glabellar lines treatment based on photographs’ evaluation by the independent assessment committee (IAC) further supported the non-inferiority conclusion of the primary efficacy endpoint, indicating that the efficacy of CU-20101 was comparable to that of BOTOX® and achieved both the primary and secondary endpoints. In terms of safety, CU-20101 demonstrated an overall favorable safety profile. There were no adverse events leading to early withdrawal from the trial or leading to death, and there were no treatment-related serious adverse events. The safety profile of CU-20101 was similar to that of BOTOX®, with no new safety signals observed.

CU-20101 will not use animal-derived materials in its manufacturing process, thereby eliminating the risk of transmissible spongiform encephalopathies (TSE) infection and related allergic reactions, and is expected to have a favorable safety advantage. CU-20101 will further enrich the Group's skin product portfolio and facilitate synergies with the Group's existing products. Facing the broad demands of the skin treatment market, a diversified product portfolio is expected to enable the Group to further increase its market share.

Warning: There is no assurance that CU-20101 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, 19 January 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.