Cutia Therapeutics

科笛集团

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

PHASE III CLINICAL TRIAL OF CU-30101 (LOCALIZED TOPICAL LIDOCAINE AND TETRACAINE CREAM) IN CHINA REACHED PRIMARY ENDPOINT

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 Phase III clinical trial of the Group's CU-30101, a localized lidocaine and tetracaine compound topical anesthesia cream for surface dermatologic operations, conducted in China reached primary endpoint. The Phase III clinical trial of CU-30101 in China enrolled a total of 286 Chinese adult patients. It was a randomized, multi-center, 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. In the Phase III clinical trial of CU-30101, Pliaglis® lidocaine and tetracaine cream ("**Pliaglis®**") served as the control drug and the reference product.

The primary efficacy endpoint of this clinical trial is Visual Analog Scale ("**VAS**") for immediate pain assessment after fractional laser surgery. VAS is one of the most commonly used pain intensity measurement assessment tools. Based on the Full Analysis Set (FAS) and Per Protocol Set (PPS) analyses, the results showed that the VAS difference (CU-30101 side-Pliaglis® side) on both sides of the face was 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 ($P>0.05$) were observed in the differences in the evaluation of "whether the two studied drugs provide the enrolled patients 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®.

CU-30101's lidocaine and tetracaine combination formulations could 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. Systemic absorption of the anesthetic component ingredients is also limited by the topical cream formulation.

Warning: There is no assurance that CU-30101 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, 31 January 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.