Cutia Therapeutics
科笛集团
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2487)

VOLUNTARY ANNOUNCEMENT

NEW DRUG APPLICATION FOR CU-40102 (TOPICAL FINASTERIDE SPRAY) 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 7 September 2023 in relation to the registrational Phase III clinical trial of CU-40102 (topical finasteride spray) conducted in the People's Republic of China (the "**PRC**") reaching primary endpoint.

The board of directors (the "**Board**") of the Company is pleased to announce that the New Drug Application (the "**NDA**") for CU-40102 (topical finasteride spray) was accepted by the National Medical Products Administration (the "**NMPA**") of the PRC. The indication of CU-40102 is for the treatment of androgenetic alopecia.

CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and the first topical finasteride to have its NDA accepted by the NMPA of the PRC. Finasteride can treat androgenetic alopecia in male patients by acting as a competitive and specific inhibitor of Type II 5-alpha reductase to inhibit the conversion of testosterone to dihydrotestosterone in the scalp. Unlike oral finasteride, CU-40102's topical formulation allows patients to apply the drug directly to the surface of the scalp, thereby maintaining a high concentration at the affected site while possibly reducing the side effects commonly associated with oral formulations.

Results of the registrational Phase III clinical trial data analysis in the PRC showed that CU-40102 has a significant efficacy for the treatment of androgenetic alopecia, and patients of the CU-40102 group showed favourable local tolerance to the administration area. Meanwhile, a Phase I pharmacokinetic study of CU-40102 in Chinese male adult patients with androgenetic alopecia conducted in the same period showed that after the administration of finasteride spray, systemic absorption was minimal in the group of Chinese androgenetic alopecia patients.

Warning: There is no assurance that CU-40102 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, 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.