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

VOLUNTARY ANNOUNCEMENT

REGISTRATIONAL PHASE III CLINICAL TRIAL OF CU-40102 (TOPICAL FINASTERIDE SPRAY) 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 registrational Phase III clinical trial of the Group's CU-40102 (topical finasteride spray) conducted in China for the treatment of androgenetic alopecia reached primary endpoint. The registrational Phase III clinical trial of CU-40102 was a multi-center, randomized, double-blind, and placebo-controlled trial to evaluate the efficacy and safety of CU-40102 in Chinese male adult patients with androgenetic alopecia.

270 Chinese male adult patients were enrolled in the registrational Phase III clinical trial of CU-40102 in China, in which 180 patients were randomly assigned to the CU-40102 group and 90 patients were assigned to the placebo group. During the 24-week continuous treatment period, patients were topically administered with CU-40102 on the local scalp area once a day.

Results of the clinical trial showed that, in terms of efficacy, improvement of the total hair count and terminal hair count in the targeted bald area of the CU-40102 group was significantly better than that of the placebo group after 24 weeks of treatment, reaching primary endpoint and key secondary endpoint and efficacy began to show from week 12. In terms of safety, patients of the CU-40102 group showed favourable local tolerance to the administration area, and the overall incidence of adverse events in the CU-40102 group was similar to that of the placebo group. Efficacy and safety results of the registrational Phase III clinical trial of CU-40102 in China are also similar to that of the overseas clinical trials.

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 is minimal in the group of Chinese androgenetic alopecia patients.

CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and currently the only topical finasteride under clinical development in China. 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.

Warning: There is no assurance that CU-40102 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, 7 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.