**開拓藥業有限公司 ***

**KINTOR PHARMACEUTICAL LIMITED**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock code: 9939)**

# VOLUNTARY ANNOUNCEMENT

# LONG-TERM SAFETY PHASE III CLINICAL TRIAL OF KX-826 FOR THE TREATMENT OF AGA REACHED PRIMARY ENDPOINT

This is a voluntary announcement made by Kintor Pharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") to update its shareholders and potential investors on the latest developments related to the Group.

Reference is made to (i) the voluntary announcement of the Company dated 19 July 2023 in relation to a long-term safety phase III clinical trial (the "**Long-term Safety Clinical Trial**") of KX-826 for the treatment of androgenetic alopecia ("**AGA**") which completed the first subject enrollment on 19 July 2023; and (ii) the voluntary announcement of the Company dated 16 October 2024 which sets out clinical trial data of some patients who completed 52 weeks' treatments.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the long-term safety phase III clinical trial of its in-house developed and potential first-in-class KX-826 tincture for the treatment of AGA has obtained top-line results. Results indicated that the Long-term Safety Clinical Trial has reached its primary endpoint with statistically significant and clinically meaningful outcomes, demonstrating excellent safety and efficacy.

The Long-term Safety Clinical Trial is a multi-center, open-label study designed to evaluate the long-term safety of the topical use of KX-826 for the treatment of AGA patients in China (treatment period of 52 weeks). The Long-term Safety Clinical Trial involves a total of 16 clinical research centers in China, with Professor Jianzhong Zhang (張建中) from Peking University People's Hospital as the lead principal investigator. The primary endpoint of the trial is the incidence of treatment-emergent adverse events ("**TEAE**") occurred during the

study. Secondary endpoints include efficacy as measured by the change in the target area non-vellus hair counts ("**TAHC**") from baseline and other safety indicators. This trial adopted KX-826 tincture 0.5% BID (i.e. twice a day) as the drug-related dosage. Results of the clinical trial showed that

- Regarding safety, KX-826 tincture exhibited satisfactory safety and tolerability in clinical trial, with a low incidence of overall adverse events and no death case. No drug-related sexual dysfunction adverse reactions were observed during the entire study period, which indicated an excellent favorable safety profile without observing any safety signals.

- In terms of efficacy, after 52 weeks' treatment, patients showed positive signals in both TAHC and target area non-vellus hair width ("**TAHW**") with an increase from baseline, demonstrating effective treatment, and the results are statistically significant ($P<0.0001$). Among the target populations, at 52 weeks, the patients with $\geqslant 10$ hairs/cm$^2$ change in TAHC from baseline accounted for 46%, the patients with $\geq 20$ hairs/cm$^2$ change accounted for 20%.

  The hair growth assessment ("**HGA**") indicators from investigators and patients both experienced various degrees of improvement from baseline, with a significant therapeutic effect. The results showed that after the treatment of 52 weeks, the efficacy rates (HGA score $\geq 1$) as assessed by HGA investigators in male patients was 53%, and the efficacy rates as assessed by HGA investigators in female patients was 48.4%. In the self-assessments at different time points, patients also demonstrated a positive trend of change in therapeutic efficacy.

**Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:** Apart from the cosmetic product of 826 topical anti-hair loss solution, there is no assurance that other products of KX-826 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
**KINTOR PHARMACEUTICAL LIMITED**
**Dr. Youzhi Tong**
*Chairman of the Board, Executive Director and Chief Executive Officer*

Hong Kong, 20 March 2025

*As at the date of this announcement, the executive Directors are Dr. Youzhi Tong and Dr. Xiang Ni; the non-executive Directors are Mr. Weipeng Gao and Ms. Geqi Wei; and the independent non-executive Directors are Dr. Michael Min Xu, Mr. Wallace Wai Yim Yeung and Prof. Liang Tong.*

** For identification purpose only*