**開拓藥業有限公司 ***

**KINTOR PHARMACEUTICAL LIMITED**

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

**(Stock code: 9939)**

# VOLUNTARY ANNOUNCEMENT

# SUPERIOR EFFICACY OF CLINICAL OBSERVATIONAL STUDY IN KX-826 IN COMBINATION WITH MINOXIDIL FOR THE TREATMENT OF MALE ADULTS WITH AGA IN CHINA OVER MINOXIDIL MONOTHERAPY

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 the voluntary announcement of the Company dated 1 February 2024 in relation to the phase Ib/III clinical trial of KX-826 in combination with minoxidil for the treatment of male adults with androgenetic alopecia ("**AGA**") in China. The clinical trial received the clearance by the National Medical Products Administration and aims to evaluate the efficacy and safety of KX-826 in combination with minoxidil for the treatment of male adults with AGA in China. In order to obtain assessments of efficacy, dosage, and patients number prior to conducting a large-scale phase III clinical trial, so as to optimize the design of phase III clinical trial protocol and ensure future clinical success, the Company initiated a clinical observational study (the "**Clinical Observational Study**") of KX-826 in combination with minoxidil for the treatment of male adults with AGA in China in March 2024 under the collaboration with two domestic hospitals.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Clinical Observational Study has reached the primary endpoint. The Clinical Observational Study is an open-label, randomized controlled study to evaluate the efficacy and safety of KX-826 in combination with minoxidil for the topical treatment of male adults with AGA in China, and to optimize the design of the formal future phase

III clinical trial protocol, including key factors such as dose selection and patient enrollment number, based on the study results.

The Clinical Observational Study involves a total of 2 clinical research centers in China, with Professor Leiwei Jiang (江蕾薇) from First People's Hospital of Guiyang and Professor Jinzhe Hu (金哲虎) from Yanbian University Hospital as the lead principal investigator. The primary endpoint of the study is the change in the target area non-vellus hair counts ("**TAHC**") from baseline after 24 weeks' treatment. Secondary endpoints include the hair growth assessment ("**HGA**") from investigators and patients. Safety indicators include adverse events, clinical laboratory test and assessment of local tolerance. A total of 75 male patients with AGA in China were enrolled in the study and were randomly assigned to KX-826 tincture 0.5% BID (i.e. twice a day) with minoxidil tincture 5% BID group (the "**Combination Drugs Group**") and minoxidil tincture 5% BID group (the "**Monotherapy Group**" or "**Minoxidil Group**") with 40 patients in the Combination Drugs Group and 35 patients in the Monotherapy Group. Results of the study showed that

- regarding efficacy, the Combination Drugs Group demonstrated statistically significant therapeutic efficacy and clinical significance compared to the Minoxidil Group. After 24 weeks of treatment, the TAHC of the Combination Drugs Group showed an increase of 30.54 hairs/$cm^2$ from baseline, which was 10.29 hairs/$cm^2$ more than the Minoxidil Group, with statistically significant results (P=0.0075). At week 24, there were 4 patients with TAHC change from baseline ≤0 hairs/$cm^2$, all of which are in the Minoxidil Group. At week 24, there were 49 patients with TAHC change from baseline ≥20 hairs/$cm^2$, with 30 patients in the Combination Drugs Group and 19 patients in the Minoxidil Group. At week 24, there were 11 patients with TAHC change from baseline ≥40 hairs/$cm^2$, with 10 patients in the Combination Drugs Group and 1 patient in the Minoxidil Group.

  Compared to the Minoxidil Group, the Combination Drugs Group showed a numerical increase in both HGA indicators from investigators and patients. At week 24, there were 24 patients with HGA investigators of 3, with 14 patients in the Combination Drugs Group and 10 patients in the Minoxidil Group. At week 24, there were 15 patients with HGA patients of 3, with 8 patients in the Combination Drugs Group and 7 patients in the Minoxidil Group.

- in terms of safety, the Combination Drugs Group exhibited good safety and tolerability in the Clinical Observational Study, with both groups showing comparable incidence of adverse events during the treatment. In addition, no unexpected adverse events were observed during the study.

KX-826 has a differentiated mechanism of action compared to minoxidil. Minoxidil primarily enhances nutrient supply to the scalp in hair loss areas, while KX-826 and Finasteride show an upstream-downstream mechanism, both targeting the modulation of

local androgen microenvironment. The aforesaid two key pathways have been clinically validated for their efficacy in preventing hair loss and promoting regrowth, with the combination therapy leveraging the synergistic combination of above-mentioned mechanism of action to significantly enhances AGA treatment efficacy. The clinical observational data showed that after 24 weeks of treatment, the Combination Drugs Group demonstrated a significant difference in TAHC compared to the Minoxidil Group, and its proportion in patients with TAHC change from baseline ≥20 hairs/cm² and ≥40 hairs/cm² further validates the clinical advantages of the combination therapy in the AGA field, not only significantly enhancing the clinical benefits for patients undergoing treatment, but also expanding the patient group that can benefit from it. Based on these research findings, the Company has greater confidence in the therapeutic potential of the patent-approved combination therapy and will systematically advance the phase III clinical trials in stages.

**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 raw material and cosmetic product of 826 topical anti-hair loss solution and acne cream, 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, 2 May 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*