開拓藥業有限公司 *

KINTOR PHARMACEUTICAL LIMITED

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9939)

VOLUNTARY ANNOUNCEMENT

(1) COMPLETION OF FIRST SUBJECT ENROLLMENT IN PIVOTAL CLINICAL TRIAL OF KX-826 TINCTURE 1.0% FOR THE TREATMENT OF MALE ADULT AGA IN CHINA; AND (2) UPDATES IN RELATION TO LONG-TERM SAFETY PHASE III CLINICAL TRIAL OF KX-826 FOR THE TREATMENT OF AGA

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.

COMPLETION OF FIRST SUBJECT ENROLLMENT IN PIVOTAL CLINICAL TRIAL

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that on 15 October 2024, the Company has completed the first subject enrollment in the pivotal clinical trial (the "**Pivotal Clinical Trial**") of its in-house developed and potential first-in-class KX-826 tincture 1.0% for the treatment of male adult androgenetic alopecia ("**AGA**") in China. The Pivotal Clinical Trial is a multi-center, randomized, double-blind, vehicle controlled phase II/III study with adaptive designs to evaluate the efficacy and safety of KX-826 tincture 1.0% for the topical treatment of male adults with AGA in China.

The Pivotal Clinical Trial adopts a phase II/III operational seamless design, namely 2-in-1 design, with Professor Jianzhong Zhang (張建中) and Professor Cheng Zhou (周城) from Peking University People's Hospital as the lead principal investigator. The Pivotal Clinical Trial includes two phases,

phase II dose exploration stage (the "**Phase II Stage**") and phase III confirmatory stage (the "**Phase III Stage**"). The Phase II Trial is expected to involve 10 clinical research centers in China, whereas the Phase III Trial is expected to involve 25 clinical research centers in China.

The Phase II Stage involves three treatment groups, namely, KX-826 tincture 0.5% BID (twice-a-day) group (low-dose group), KX-826 tincture 1.0% BID group (high-dose group), and KX-826 tincture vehicle group (control group) in a 1:1:1 allocation ratio. 30 patients will be enrolled in each group (i.e. 90 patients will be enrolled in total), who will receive treatment with the stipulated dosages over a period of 24 weeks.

The Phase III Stage involves three treatment groups, namely, KX-826 tincture 0.5% BID group (low-dose group), KX-826 tincture 1.0% BID group (high-dose group), and KX-826 tincture vehicle group (control group) in a 1:1:1 allocation ratio. 222 patients will be enrolled in each group (i.e. 666 patients will be enrolled in total), who will receive treatment with the stipulated dosages over a period of 24 weeks.

The Company's preclinical studies have shown that the KX-826 tincture 1.0% has significantly increased the retention concentration of the tincture on human scalp cells compared to the KX-826 tincture 0.5% used in the previous phase III clinical trial, and is expected to enhance the clinical efficacy. The clinical trial of KX-826 tincture 1.0% is expected to maintain excellent safety profile and present superior efficacy compared to the KX-826 tincture 0.5%.

UPDATES IN RELATION TO LONG-TERM SAFETY PHASE III CLINICAL TRIAL

Reference is made to the 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 AGA, which completed the first subject enrollment on 19 July 2023.

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 as the drug-related dosage. The analysis results of 95 male patients who completed 52 weeks' treatments showed:

- Regarding safety, KX-826 tincture demonstrated great safety and tolerability as a whole, without any serious adverse events ("**SAE**") related to the drug reported. The common (incidence≥5%) treatment related adverse events ("**TRAE**") were itching at application sites, and most of them were mild, not affecting the daily life of patients.

- In terms of efficacy, after 12, 24, 36 and 52 weeks' treatment, both TAHC and target area non-vellus hair width ("**TAHW**") showed an increase from baseline, among which, the TAHC increased by 9.5%, 13.0%, 11.4% and 9.7% respectively, TAHW increased by 12.1%, 18.6%, 15.7% and 10.0% respectively, with statistically significant results. Such results were significantly better than the results from the previous 0.5% phase III clinical trial at 24 weeks.

  At 24 weeks, the patients with ≥ 10 hairs/cm^2 change in TAHC from baseline accounted for 60.2%, the patients with ≥ 20 hairs/cm^2 change accounted for 28.9%, the patients with ≥ 30 hairs/cm^2 change accounted for 18.0%. At 52 weeks, the patients with ≥ 10 hairs/cm^2 change in TAHC from baseline accounted for 48.4%, the patients with ≥ 20 hairs/cm^2 change accounted for 20.4%, the patients with ≥ 30 hairs/cm^2 change accounted for 11.8%.

  The hair growth assessment ("**HGA**") indicators from investigators and patients both experienced various degrees of improvement from baseline, demonstrating a trend in efficacy. The results showed that as assessed by investigators, 60.9%, 69.5%, 64.0% and 54.0% of patients saw improvements in their hair growth from baseline after the treatment of 12, 24, 36 and 52 weeks respectively (HGA score ≥1).

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, 16 October 2024

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*