Kintor Pharma Announced the Primary Endpoint of Phase II Clinical Study for KX-826's Treatment of Female Androgenetic Alopecia in China Was Met

Suzhou, December 1, 2022 - Kintor Pharmaceutical Limited ("Kintor Pharma", HKEX: 9939), a clinical-stage biotechnology company developing innovative small molecules and biological therapeutics, today announced results of phase II clinical trial of pyrilutamide (KX-826), a potential first-in-class topical drug developed by the company, in China for the treatment of adult female androgenetic alopecia (AGA). In the study, KX-826 has demonstrated clinically meaningful and statistically significant improvement in hair growth as measured by target area non-vellus hair count (TAHC). In addition, its safety profile was favorable.

This trial is a multi-center, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of KX-826 for the treatment of AGA in female adults. Professor Jianzhong Zhang, chairman of the Department of Dermatology, Peking University People's Hospital, is the leading principal investigator (Leading PI). The primary endpoint for the trial is the change from baseline versus placebo in TAHC at the end of week 24.

A total of 160 female AGA patients who have met Savin Scale (D3-D6) were enrolled in the phase II clinical trial. 119 patients were randomly assigned to four treatment groups, including KX-826 2.5mg (0.25%) once daily (QD), KX-826 2.5mg (0.25%) twice daily (BID), KX-826 5mg (0.5%) QD and KX-826 5mg (0.5%) BID; and 41 patients were assigned to placebo groups (QD and BID). The results haven shown that,

- The TAHC of the KX-826 5mg (0.5%) QD group has increased by 11.39 hair counts per cm^2 compared with the placebo group from baseline after the treatment of 24 weeks, which was statistically significant (P=0.0087). In addition, KX-826 has demonstrated efficacy as early as at the end of week 12.

- The recommended dose for phase III clinical trial for female AGA in China is determined as KX-826 5mg (0.5%) QD.

- The overall safety profile of KX-826 was favorable. The majority of treatment emerged adverse events (TEAE) were mild and similar to those of placebo. No TEAE resulted in patient withdrawal from the trial, nor death was reported.

Professor Jianzhong Zhang, chairman of the Department of Dermatology, Peking University People's Hospital, commented, "AGA is the most common type of hair loss greatly affecting male and female adults. The market potential for unmet medical needs is huge. In particular, treatment options for female AGA adults are more limited than those for male AGA adults. We are pleased to announce that the first-in-class topical drug, KX-826, has shown a good efficacy and safety profile in the female AGA phase II trial. This result paves the way for the pivotal study which would kick off very soon. Meanwhile, the enrollment of pivotal study of KX-826 for treating male AGA adults is ongoing in China. We look forward to KX-826's commercialization to provide benefits to both male and female AGA adults worldwide."

Dr. Youzhi Tong, founder, Chairman and Chief Executive Officer of Kintor Pharma, commented, "1) Compared with the clinical trial design for male AGA adults study, it is more challenging for the phase II clinical trial of treating female AGA adults, due to changes in their hairline shape, hair loss rating and hair density and lack of detectable biomarkers; 2) Minoxidil and Finasteride are available for male AGA adults, however, for female AGA adults, the topical treatment is limited to Minoxidil only; 3) Even the incidence rate is 1 in 20 for female AGA adults, which is less than that for male, women have a higher desire for appearance and are willing to pay. Therefore, the market size of treating female AGA is large in both China and overseas. We expect to kick off the pivotal study in China soon. In the meantime, we will continue to actively look for partners to expand into the international market. We hope that KX-826 would be an effective and safe first-in-class drug for male and female AGA adults around the globe as soon as possible."

About KX-826

KX-826 is an androgen receptor (AR) antagonist and a potential first-in-class topical drug for the treatment of AGA and acne vulgaris. For the AGA indication, on 8 September 2021, Kintor Pharma announced that the primary endpoint of the phase II clinical trial of KX-826 on male adults was met, with results demonstrating a positive efficacy and safety profile. Kintor Pharma is continuing to conduct a phase III clinical trial of KX-826 in China and has completed the enrollment of patients in its phase II clinical trial of KX-826 in the US for male AGA adults. For the acne vulgaris indication, Kintor Pharma has completed the enrollment of patients in its phase II clinical trial of KX-826 in China.

About Kintor Pharmaceutical Limited

Kintor Pharmaceutical Limited is developing and commercializing a robust pipeline of innovative small molecule and biological therapeutics for androgen-receptor-related disease areas with unmet medical needs, including

COVID-19, prostate, breast and liver cancers, alopecia and acne. For more information, visit www.kintor.com.cn.