Kintor Pharma Announces Positive Top-line U.S. Phase I Trial Results of GT20029, the World's First Topical Use PROTAC Compound

Suzhou, February 10, 2023 - Kintor Pharmaceutical Limited ("Kintor Pharma", HKEX: 9939), a clinical-stage biotechnology company developing innovative small molecules and biological therapeutics, announced the positive top-line results from the U.S. Phase I clinical trial of GT20029, a Kintor Pharma in-house developed and fully owned proteolysis targeting chimera (PROTAC) compound. The data showed GT20029 was safe, well tolerated and had good pharmacokinetic characteristics in healthy subjects as well as subjects with androgenetic alopecia (AGA) or acne. GT20029 is the first topical PROTAC compound in the world which has completed Phase I clinical trial in both China and the U.S..

This is a randomized, double-blind, placebo-controlled, parallel group, dose escalation Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of GT20029 following topical single ascending dose administration (SAD) in healthy subjects and multiple ascending dose administration (MAD) in subjects with AGA or acne.

The results showed that GT20029 was safe and well tolerated at all dose levels in all cohorts. No treatment-emergent adverse events (TEAEs) related to GT20029 in the SAD stage were reported. The most common TEAEs in the MAD stage were mild, including dryness, itching, burning and pain at application site. No serious adverse events (SAEs) were reported. No severe (Grade ≥3) TEAEs and no subject withdrawal or death caused by TEAEs were reported.

In the SAD stage, subjects had no systemic exposure at all dose levels, and all sample concentrations were below the lower limit of quantification (LLOQ, 0.003ng/mL). In the MAD stage, after 14 days of continuous administration in subjects with AGA or acne, the systemic exposure was very limited and the mean maximum observed concentration (Cmax) of all dose levels fluctuated near the LLOQ, with the highest not exceeding 0.015 ng/mL.

In preclinical studies, by degrading androgen receptor (AR) protein, GT20029 could block the shrinkage and miniaturization of hair follicles which was caused by the activation of AR signaling pathway. As the result, it prevented the hair from thinning, softening

and falling out. GT20029 could also effectively inhibit sebaceous gland development and sebum secretion. With limited skin penetration, GT20029 could avoid high systemic exposure and achieve a better safety profile. The repeated pharmacodynamics studies in dihydrotestosterone (DHT)-induced mouse model showed that GT20029 significantly promoted hair growth, with statistical difference. The study of testosterone propionate (TP)-induced skin hamster flank organ acne model showed that GT20029 significantly inhibited enlargement of flank organ, with statistical difference.

Dr. Youzhi Tong, founder, Chairman and Chief Executive Officer of Kintor Pharma, commented, “The positive U.S. Phase I top-line results of GT20029 in 123 subjects has shown a similar result with that of Phase I trial in China with 92 subjects enrolled. Both studies have demonsrtated the good safety and tolerability in MAD of GT20029. Alopecia affects about 1.6 billion people and acne affects about 0.72 billion people worldwide, there are huge unmet clinical needs. We will accelerate the initiation of Phase II clinical trial of GT20029, maintain our leading position in the development of topical PROTAC drug candidate globally. We believe that GT20029 would strengthen our market position in the dermatology area,

together with our novel drug KX-826, to provide a diversified portfolio of therapies to patients with AGA or acne. ”

About GT20029

GT20029 is a topical AR degrader developed by Kintor Pharma’s PROTAC platform. The China National Medical Products Administration (NMPA) and the U.S. Food and Drug Administration (FDA) cleared GT20029's clinical trial applications for treating AGA and acne in April 2021 and July 2021, respectively. In August 2022, Kintor Pharma had completed the enrollment and dosing of subjects for its China Phase I clinical trial. In November 2022, Kintor Pharma announced the top-line results for its China Phase I clinical trial. In October 2022, Kintor Pharma announced completion of subject enrollment and dosing in its U.S. Phase I clinical trial.

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.