開拓藥業有限公司*

KINTOR PHARMACEUTICAL LIMITED

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9939)

ANNOUNCEMENT
INSIDE INFORMATION

INTERIM ANALYSIS FOR PHASE III STUDY OF PROXALUTAMIDE FOR PATIENTS WITH MILD TO MODERATE COVID-19 SYMPTOMS

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

References are made to the announcements of the Company dated 5 March 2021, 25 April 2021 and 18 May 2021, respectively (the "**Announcements**"). Unless the context requires otherwise, the capitalised terms used in this announcement shall have the same meanings as defined in the Announcements.

The Company would like to provide an update on its multi-regional study of proxalutamide for the treatment of COVID-19 infection for outpatients (NCT04870606) (the "**Phase III Study**") as at 27 December 2021. Statistical criteria were not met at an interim analysis of the Phase III Study, designed for testing efficacy and safety of proxalutamide for treating non-hospitalized COVID-19 patients. The Company will seek for regulatory authorities including the U.S. Food and Drug Administration's (FDA) consent to amend the protocol and continue to enroll higher risk COVID-19 patients only with multiple comorbidities and/or patients with no COVID-19 vaccination history. Based on the interim analysis, there were no safety concerns and no drug-related serious adverse events (SAEs) reported during the study.

As at 23 December 2021, we have completed the enrollment of the Phase III Study according to the original protocol. More than 95% of the enrolled patients were from the U.S. For the interim analysis, all patients were from the U.S., where the hospitalisation rate is very low.

As the COVID-19 pandemic continues to evolve with the Omicron variant highlighting the need for therapeutics, it is important to investigate new modalities to treat those infected with the virus. The Company believes proxalutamide could become an important tool in the fight against COVID-19 infection and will continue to investigate its use. The Company would provide updates on the final data analysis from this outpatient clinical trial in due course.

The outpatient study is a randomized, double-blind, placebo-controlled Phase III study designed to evaluate the efficacy and safety of proxalutamide in outpatients with mild to moderate COVID-19 illness. For the interim analysis, the trial enrolled 348 male and female patients with one or more mild COVID-19-related symptoms within five days of symptoms onset. Participants were randomized to receive proxalutamide (200 mg) or placebo orally twice daily for 14 days. The enrolment criteria did not exclude vaccinated patients nor exclude patients without risk factors. Both the treatment arm and placebo arm were given standard of care. The primary endpoint was the percentage of all-cause death and hospitalization for a period exceeding 24 hours by day 28.

As at the date of this announcement, the Company is conducting two registered Phase III multi-regional clinical trials (MRCT) of proxalutamide for the treatment of COVID-19 outpatients (NCT04870606 and NCT04869228), and one Phase III MRCT for COVID-19 inpatients (NCT05009732) in countries and regions that include the United States, South America (including Brazil), Asia (including China) and the European Union. The Company has received emergency use authorisation (EUA) for proxalutamide for the treatment of COVID-19 infection in hospitalized patients in Paraguay.

Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that proxalutamide 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, Executive Director and Chief Executive Officer

Hong Kong, 27 December 2021

As of the date of this announcement, the executive Director is Dr. Youzhi Tong; the non-executive Directors are Mr. Gang Lu, Mr. Weipeng Gao, Dr. Yan Wang 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*