開拓藥業有限公司*

KINTOR PHARMACEUTICAL LIMITED

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9939)

INSIDE INFORMATION

TOP-LINE RESULTS FROM PROXALUTAMIDE PHASE III CLINICAL TRIAL FOR TREATING OUTPATIENTS WITH MILD TO MODERATE COVID-19

This announcement is made by Kintor Pharmaceutical Limited (the "**Company**") pursuant to the Inside Information Provisions under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) and Rule 13.09 of the Rules Governing the Listing of Securities (the "**Listing Rules**") on The Stock Exchange of Hong Kong Limited.

The board (the "**Board**") of directors (the "**Directors**") is pleased to announce the top-line data of the phase III study of proxalutamide in treating outpatients with mild to moderate COVID-19 (NCT04870606) (the "**Clinical Trial**"). The Clinical Trial is a double-blind, placebo-controlled, randomized (1:1), multi-center registrational trial. The first subject was enrolled on 24 April 2021, the enrollment of a total of 733 subjects across the world (727 of which were from the United States, and the remaining were from other countries) was completed on 24 December 2021, and the last subject's last visit occurred on 3 February 2022. The subjects were prescribed either proxalutamide 200mg, once daily (QD) plus standard of care ("**SOC**") ("**proxalutamide arm**" or "**proxalutamide group**") or placebo plus SOC ("**placebo arm**" or "**controlled group**") for 14 consecutive days. Subjects with COVID-19 symptom onset within 5 days were enrolled, whether or not any risk factors were present, and subjects who have been vaccinated against COVID-19 were not excluded.

The study endpoints of the Clinical Trial included the percentage of subjects who did not experience all-cause hospitalization for at least 24 hours, or did not require supplemental oxygen for at least 24 hours in response to SpO2 ≤93% and were alive by Day 28; the proportion of subjects with all-cause hospitalization (defined as ≥24 hours), requiring supplemental oxygen or all-cause mortality by Day 28, and changes of SARS-CoV-2 viral load from baseline to Day 28 as well as safety assessments.

The top-line data of the Clinical Trial is summarized as following:

EFFICACY

Proxalutamide effectively reduced the risk of hospitalization/death

- Among all randomized subjects with at least one day of study treatment (N=730), 8 subjects in the placebo arm were hospitalized (including one death) as compared to 4 subjects in the proxalutamide arm (no death). Proxalutamide reduced the risk of hospitalization or death by 50% as compared to the controlled group (all hospitalizations were COVID-19 related).

- Among subjects with more than 1 day of treatment (N=721), 7 subjects in the placebo arm were hospitalized (including one death) as compared to 2 subjects (no death) in the proxalutamide arm. Proxalutamide reduced the risk of hospitalization or death by 71% as compared to the controlled group.

- Among subjects with more than 7 days of treatment (N=693), 6 subjects in the placebo arm were hospitalized (including one death) as compared to no hospitalization/death ($p < 0.02$) in the proxalutamide arm. Proxalutamide reduced the risk of hospitalization or death by 100% compared to the controlled group.

Proxalutamide significantly reduced the risk of hospitalization/death in subjects with high risk factors, especially medium to high age group

- Within the subjects aged ≥50 years with obesity, proxalutamide significantly reduced the risk of hospitalization/death by 100% ($p<0.02$), as there was no hospitalization or death in the proxalutamide group.

- Within the subjects aged ≥60 years with or without underlying medical conditions, proxalutamide significantly reduced the risk of hospitalization or death by 100% ($p<0.02$), as there was no hospitalization or death in the proxalutamide group.

- Within the subjects aged ≥60 years with at least one underlying medical condition (such as obesity, diabetes, hypertension, etc.), proxalutamide significantly reduced the risk of hospitalization or death by 100% ($p<0.02$), as there was no hospitalization or death in the proxalutamide group.

Proxalutamide significantly and continuously reduced SARS-CoV-2 viral load

- As compared to the controlled group, proxalutamide significantly and continuously reduced SARS-CoV-2 viral load from Day 3 to Day 28 ($p<0.01$ on Day 3 and Day 28, respectively).

Proxalutamide improved COVID-19 related symptoms

- With respect to improvements in symptoms, proxalutamide group showed better improvements in certain COVID-19 related symptoms such as fever, shortness of breath, cough until at least Day 28 as compared to the controlled group.

SAFETY

The Clinical Trial demonstrated that proxalutamide was well tolerated and manageable in subjects with mild to moderate COVID-19 symptoms. The incidence of treatment-emergent adverse events (TEAE) were 7.9% and 9.6% respectively in the controlled group and proxalutamide group, the majority of which was mild. The most common adverse event was dizziness (1.1% in both proxalutamide and controlled groups), the incidence of any of the remaining adverse events was less than 1%. There was no serious adverse event in the study.

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, 6 April 2022

As of the date of this announcement, the executive Director is Dr. Youzhi Tong and Ms. Yan Lu; the non-executive Directors are 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*