Hong Kong Stock Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



開拓藥業有限公司*

KINTOR PHARMACEUTICAL LIMITED

(Incorporated in the Cayman Islands with limited liability) (Stock code: 9939)

VOLUNTARY ANNOUNCEMENT CLINICAL TRIAL COLLABORATION IN COVID-19 STUDY OF PROXALUTAMIDE

This is a voluntary announcement made by Kintor Pharmaceutical Limited (the "**Company**" and together with its subsidiaries, the "**Group**").

On 7 July 2020, Suzhou Kintor Pharmaceutical, Inc.* (蘇州開拓藥業股份有限公司) ("Suzhou Kintor"), a wholly-owned subsidiary of the Company, and Applied Biology, Inc. ("Applied Biology") entered into a clinical trial research agreement ("Research Agreement"), pursuant to which Suzhou Kintor engages Applied Biology to conduct research for Proxalutamide (GT0918) as a treatment for the coronavirus disease ("COVID-19").

Applied Biology, a company established in 2002 under the laws of the State of California, the United States, is a biotechnology company specialising in the development and research of breakthrough drugs and devices for the treatment of androgen and hair disorders. Professor Dr. Andy Goren ("**Dr. Goren**"), whose publications have shown observations on a potential association between androgenetic alopecia and COVID-19 pathogenesis, currently serves as the Chief Medical Officer of Applied Biology. Dr. Goren currently also serves as a Medical Advisor and Co-Investigator of Department of Dermatology, The Warren Alpert Medical School, Brown University. Dr. Goren has published dozens of peer-reviewed original medical research papers, and his latest research involves the use of anti-androgen therapy for the treatment of COVID-19. His clinical research has provided the scientific rationale for the early pharmacological interventions with therapeutic agents targeting androgen receptor pathway in COVID-19 patients.

Preliminary clinical researches and observations reveal a potential association between androgenetic alopecia and COVID-19 pathogenesis, which prompted Applied Biology to test anti-androgens as a treatment for male patients recently diagnosed with COVID-19. The clinical trial (ClinicalTrials.gov identifier: NCT04446429) was registered by Applied Biology in accordance with the United States Food and Drug Administration Amendments Act of 2007 and the requirements of the International Committee of Medical Journal Editors in June 2020 (the "**Existing Clinical Trial**"). For the purpose of exploring the possible protective role of anti-androgenesic alopecia are estimated to be enrolled in this double-blinded and placebo controlled study. The experimental arm (50% of the participants) will be treated with Dutasteride plus standard care (Ivermectin + azithromycin) and the control arm (50% of the participants) will be treated with placebo plus standard care. Dutasteride is a medication used for benign prostatic hyperplasia and off-label for androgenetic alopecia in men. Ivermectin + azithromycin are used as standard care given there has been no approved medication for coronavirus patients. The primary end point of the study is percentage of subjects hospitalised due to COVID-19 within 30 days.

Pursuant to the Research Agreement, Applied Biology includes Proxalutamide (GT0918) as an additional arm of 120 male study subjects to the Existing Clinical Trial, and is expected to complete the proposed research in six to nine months of the signing of the Research Agreement. Applied Biology tailors a research protocol for Proxalutamide (GT0918) which is subject to independent ethic committee and institutional review board's approval. Dr. Goren as the principal investigator will supervise the research and ensure its compliance with general standard of good clinical practice and all applicable laws and regulations. The findings of the research are to be submitted for peer-reviewed and indexed publication. The research helps demonstrate the Company's commitment to social responsibilities as a biotech company and the possible therapeutic effect of Proxalutamide as an anti-androgen therapy to treat COVID-19. According to Dr. Goren, provided the research demonstrates its efficacy and safety, Proxalutamide could potentially be used as a first line treatment for COVID-19 male patients at the early stage of infection.

Proxalutamide (GT0918) is the Group's lead drug candidate and is in phase III clinical trials in China for metastatic castration-resistant prostate cancer ("**mCRPC**") with a targeted submission of new drug application in 2020. It is also undergoing phase II clinical trials for mCRPC in the United States. Proxalutamide (GT0918) is a potential best-in-class small molecule AR antagonist for the treatment of mCRPC based on well-researched AR mechanism and has a novel chemical structure that enables it to down regulate AR expression.

The Group's recent pre-clinical research collaboration with Soochow University in exploring the potential mechanism of COVID-19 gender disparity revealed that the blockage of AR signalling with AR antagonist Proxalutamide (GT0918) reduced the expression of ACE-2 and TMPRSS2 in normal lung cells and cancer cells derived from prostate and lung cancer. Proxalutamide (GT0918) also inhibited the expression of inducible nitric oxide synthase (iNOS) and tumour necrosis factor-alpha (TNF α), the macrophage-activation markers, in mouse macrophage cells. These results support the role of androgen-AR signalling in the disease progression and mortality in male patients with COVID-19 and were published on the SSRN on 23 April 2020. The collaboration with Applied Biology can further explore the therapeutic function of Proxalutamide (GT0918).

To the best knowledge of and based on the information available to the Company, as at the date of this announcement, Dr. Goren, Applied Biology and its subsidiaries are third parties independent of the Company and connected persons of the Company within the meaning of The Rules Governing Listing of Securities on The Stock Exchange of Hong Kong Limited.

By order of the Board **KINTOR PHARMACEUTICAL LIMITED Dr. Youzhi Tong** *Executive Director*

Hong Kong, 12 July 2020

As of the date of this announcement, the executive Director is Dr. Youzhi Tong; the non-executive Directors are Dr. Chuangxing Guo, Mr. Gang Lu, Mr. Jie Chen, Dr. Bing Chen and Ms. Xiaoyan Chen; and the independent non-executive Directors are Dr. Michael Min Xu, Dr. John Fenyu Jin and Mr. Wallace Wai Yim Yeung.

* For identification purpose only