Laekna, Inc.

來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2105)

VOLUNTARY ANNOUNCEMENT

APPROVAL BY THE U.S. FOOD AND DRUG ADMINISTRATION FOR THE PHASE III CLINICAL TRIAL PROTOCOL OF LAE002 (AFURESERTIB) PLUS LAE001 FOR THE TREATMENT OF PROSTATE CANCER

This announcement is made by Laekna, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business update of the Group.

The board (the "**Board**") of directors of the Company (the "**Directors**") is pleased to announce that the Group has received approval from the U.S. Food and Drug Administration (the "**U.S. FDA**") for the protocol of the phase III clinical trial of LAE002 (afuresertib, an AKT inhibitor) plus LAE001 (CYP17A1/CYP11B2 dual inhibitor) ("**LAE201**") in patients with metastatic castration-resistant prostate cancer ("**mCRPC**") following standard of care ("**SOC**") treatment.

We initiated a Phase II multi-region clinical trial of the study of LAE201 in patients with mCRPC following SOC treatment in the U.S. in June 2021, and South Korea in September 2022. The trial is an open-label, dose-escalation and dose expansion study to assess the efficacy and safety of the combination candidate. The study demonstrated promising treatment benefit for mCRPC patients. As of 21 November 2023, 40 patients who progressed on 1–3 lines of standard treatments, including at least 1 line of abiraterone, or the second generation of AR antagonists, had been enrolled in the recommended phase II dose group. The median rPFS was 8.1 months. This is a significant improvement compared to the median rPFS of 2 to 4 months of mCRPC patients under the standard treatments historically. The combination therapy was generally tolerable with manageable treatment emergent adverse events and recoverable after routine treatments. A following Phase III pivotal trial design has been discussed with the U.S. FDA and the approval for the protocol was received in May 2024.

The Group plans to bring this precision therapy to mCRPC patients who are in need of novel treatment options.

RISK WARNING

LAE201 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED. THE COMPANY'S SHAREHOLDERS AND POTENTIAL INVESTORS ARE REMINDED TO EXERCISE CAUTION WHEN DEALING IN THE SECURITIES OF THE COMPANY.

By order of the Board
Laekna, Inc.
Dr. LU Chris Xiangyang
Chairman

Hong Kong, 23 May 2024

As at the date of this announcement, the Board comprises Dr. LU Chris Xiangyang, Ms. XIE Ling and Dr. GU Xiang-Ju Justin as executive Directors; Dr. WANG David Guowei and Mr. SUN Yuan as non-executive Directors; and Dr. YIN Xudong, Dr. LI Min and Mr. ZHOU Jian as independent non-executive Directors.