Laekna, Inc.

來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2105)

VOLUNTARY ANNOUNCEMENT PRESENTATION OF THE STUDY RESULTS FROM CORE PRODUCT AFURESERTIB (LAE002) AT THE 2023 SABCS

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 of directors of the Company (the "**Board**") announces that the results of a phase Ib study to evaluate the efficacy and safety of afuresertib (LAE002, an oral pan-AKT inhibitor) plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer who failed standard of care therapies were presented during a poster spotlight session at the 2023 San Antonio Breast Cancer Symposium (SABCS). The study results are summarized as follows:

LAE205INT3101 (NCT04851613) is an ongoing phase Ib/III global study. The data presented is from the phase Ib single arm, open-label study to evaluate the efficacy and safety of the combination therapy of afuresertib (125mg QD) plus fulvestrant (500mg Q28 days) in patients with HR+/HER2- LA/mBC who have disease progression after 1–2 prior lines of ET with or without a CDK4/6 inhibitor (≤1 line), and/or ≤1 line of chemotherapy.

As of the data cut-off date of October 16, 2023, 20 patients were enrolled, including 17 Chinese patients and 3 American patients. There were 19 female patients and 1 male patient enrolled. The median age of all patients was 53 years old. 80% of the patients had received one line of therapy, and 20% had received two lines of therapy. 70% of the patients were previously treated with CDK4/6 inhibitors. The median duration of follow-up was 11 months.

- Efficacy.
  - — Best overall response：6 patients had confirmed partial response (30%), 10 patients had stable disease (50%), and 4 patients had progressive disease (20%).
  - — The confirmed objective response rate was 30% (95%CI, 11.9, 54.3) and the disease control rate was 80%. The median PFS was 7.3 months (95%CI, 3.7, NE).

— Among the 11 patients with specific biomarker alterations (PIK3CA/AKT1/PTEN), the confirmed objective response rate was 45.4% (95%CI, 16.7, 76.6), the disease control rate was 82%, and the median PFS was 7.3 months (95%CI, 3.6, 8.2).

— Among the 17 Chinese patients, the confirmed objective response rate was 29.4% (95%CI, 10.3, 60.0), the disease control rate was 82.4%, and the median PFS was 7.3 months (95%CI, 3.6, 8.2).

- Safety.

— No dose modification was required during the safety run-in. No patient discontinued treatment due to TEAE. No SAE or TEAE > = Grade 4 was reported. The majority of observed TEAEs were Grade 1. Grade 3 AEs were reported in 7 patients, including diarrhea, pharyngitis, ALT/AST, γ-glutamyl transferase, creatine phosphokinase increased, white blood cell count decreased and rash.

Conclusions: The preliminary data from the combination therapy of afuresertib plus fulvestrant has shown promising efficacy with a well-tolerated safety profile in patients with HR+/HER2- LA/mBC who had disease progression after 1–2 prior lines of standard of care therapies.

Currently, the Phase III pivotal trial of afuresertib plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer who failed standard of care therapies has been initiated.

RISK WARNING

AFURESERTIB (LAE002) 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, December 11, 2023

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, Mr. CHAU Kwok Keung and Dr. LI Min as independent non-executive Directors.