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Laekna, Inc.

來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2105)

INSIDE INFORMATION

POSITIVE TOPLINE RESULTS

PHASE III CLINICAL TRIAL (AFFIRM-205) OF LAE002 (AFURESERTIB) MET PRIMARY ENDPOINT OF PFS DEMONSTRATED HIGHLY STATISTICALLY SIGNIFICANT AND CLINICALLY MEANINGFUL BENEFITS IN PATIENTS WITH PIK3CA/AKT1/PTEN ALTERATIONS AND HR+/HER2- LA/mBC

This announcement is made by Laekna, Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board (the “**Board**”) of directors of the Company (the “**Directors**”) is pleased to announce that LAE002 (afuresertib) plus fulvestrant has demonstrated strong positive topline results in the phase III clinical trial in locally advanced or metastatic HR+/HER2- breast cancer (“**LA/mBC**”) patients with PIK3CA/AKT1/PTEN alterations, following recurrence or progression on or after endocrine therapy(-ies) (with or without a CDK4/6 inhibitor) (the “**Phase III Clinical Trial (AFFIRM-205)**”). This pivotal study successfully met its primary endpoint of progression-free survival (“**PFS**”), achieving a highly statistically significant and clinically meaningful improvement versus control.

The Phase III Clinical Trial (AFFIRM-205) is a multi-center, randomized, double-blind, placebo-controlled pivotal study to assess the anti-tumor efficacy and safety of the combination therapy. A total of 261 subjects were enrolled and 70.5% of subjects were previously treated with CDK4/6 inhibitors.

- The study met its primary endpoint with a median PFS of 7.6 months for LAE002 (afuresertib) plus fulvestrant combination versus 2.0 months for placebo plus fulvestrant, HR=0.33 (p-value <0.0001).

- Treatment with oral, once-daily LAE002 (afuresertib) was well tolerated, with very low rates of discontinuation due to adverse events. The overall safety profile was consistent with previous data evaluating this combination.

The detailed study results will be presented at an upcoming international scientific conference. Based on the positive results from the phase III pivotal study, the Group will work together with Qilu Pharmaceutical Company Limited (“**Qilu Pharma**”) to submit the new drug application (“**NDA**”) for LAE002 (afuresertib) to the Center for Drug Evaluation (“**CDE**”) of China’s National Medical Products Administration (“**NMPA**”) in the near term.

The Group and Qilu Pharma entered into an exclusive licensing agreement (the “**License Agreement**”) for the China region in November 2025. Under the License Agreement, the Group is eligible to receive up to RMB2,045 million in total in upfront and milestone payments and is entitled to receive tiered royalties on future net sales of LAE002 (afuresertib) in the Licensed Territory, at percentages ranging from the low teens to the low twenties. The Group plans to pursue strategic partnerships in ex-China regions to accelerate development and commercialization of LAE002 (afuresertib) in international markets. Collectively, alterations in PIK3CA, AKT1 and PTEN affect approximately 50% of patients with breast cancer.

About LAE002 (AFURESERTIB)

LAE002 (afuresertib) is a potent AKT inhibitor that inhibits all three AKT isoforms (AKT1, AKT2 and AKT3). It is one of the only two AKT inhibitors globally in late-stage development for breast and prostate cancer. The Phase III Clinical Trial (AFFIRM-205) has met its primary endpoint of progression-free survival. It showed statistically significant and clinically meaningful benefits to patients with HR+/HER2- breast cancer.

RISK WARNING

LAE002 (AFURESERTIB) MAY ULTIMATELY NOT 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, April 15, 2026

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.