SUNSHINE LAKE PHARMA CO., LTD.

廣東東陽光藥業股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 6887)

VOLUNTARY ANNOUNCEMENT IN RELATION TO THE MARKETING APPROVAL OF INSULIN GLARGINE INJECTION BY THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

This announcement is made by Sunshine Lake Pharma Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Insulin Glargine Injection independently developed by the Group has received an approval letter issued by the U.S. Food and Drug Administration (the "**FDA**"). Relevant details are hereby announced as follows:

I. BASIC INFORMATION OF THE DRUG

1. Drug Name: Insulin Glargine Injection
2. Trade Name: Langlara
3. Dosage Form: Injection
4. Specification: 3ml: 300 units (U-100)
5. Application Number: 761412
6. Approval Number: 2343
7. Indications: For the treatment of adult and paediatric patients with type 1 diabetes and adult patients with type 2 diabetes for glycaemic control.

II. OTHER RELEVANT INFORMATION OF THE DRUG

According to reports from the U.S. Centres for Disease Control and Prevention (CDC), currently there are approximately 40 million people with diabetes in the United States, accounting for 12% of the total population, with the prevalence rate showing an upward trend. Additionally, over 100 million people are in a state of prediabetes.

Insulin Glargine is a third-generation insulin analogue and the world's first once-daily long-acting insulin analogue. It was originally developed by Sanofi under the trade name Lantus®. According to a report by QYResearch, the global market size for insulin glargine is estimated to be nearly US$10 billion, with the United States being the largest market in the world, accounting for over 60% of the market share. Currently, only the originator product from Sanofi and biosimilars from Eli Lilly and Biocon have been approved in the U.S. market, resulting in a favourable competitive landscape.

This approval is primarily based on a Phase I clinical trial conducted overseas, which demonstrated the pharmacokinetic and pharmacodynamic biosimilarity between the Group's Insulin Glargine Injection and Lantus® in healthy male volunteers through a clamp study. A total of 104 subjects were enrolled in the study, 94 of whom participated in the pharmacokinetic and pharmacodynamic research. The trial results demonstrated that the Group's Insulin Glargine Injection is biosimilar to Lantus® in terms of pharmacokinetics and pharmacodynamics. The Group successfully underwent an on-site inspection by the FDA between September and October 2025. The product has now been successfully approved and has been granted interchangeable status on its label.

Following this approval, the Company's Insulin Glargine (trade name: Langlara) has become the fourth Insulin Glargine product to be marketed in the United States, and the Company has become the first Chinese enterprise to launch an Insulin Glargine product in the U.S. market. This represents a significant milestone in the Company's internationalisation strategy.

III. THE GROUP'S GLOBAL FOOTPRINT IN INSULIN

Chinese Market: The Group has been deeply involved in the field of diabetes treatment for many years and has established a comprehensive product line of insulin biosimilars. All five insulin products independently developed by the Group have been approved for marketing, and all five products were successfully selected in the National Volume-Based Procurement programmes. In terms of production, the Group's Yidu Base possesses the capability to manufacture second- to fourth-generation insulin products, with an annual production capacity exceeding 100 million units.

U.S. Market and Order Status: The Group's Insulin Glargine Injection has successfully obtained FDA approval for marketing, and the Group is currently advancing the development of aspart insulin in the United States. In the future, the Group will leverage the well-established local commercialisation capabilities of its U.S. partner, Lannett, to achieve a rapid increase in sales volume. The Company has already secured an initial order from Lannett for Insulin Glargine Injection. Pursuant to the agreement, the Company will supply Insulin Glargine Injection to Lannett with a total order volume of at least 18 million units over a supply period of 18 months. Meanwhile, the Group is also actively exploring other commercialisation channels in the United States.

Global Market: The Group's insulin product line has taken a lead in commercial breakthroughs in emerging markets such as the Middle East, Southeast Asia, South America, and West Africa. The U.S. FDA's review standards have long been recognised as the "gold standard" for evaluating the quality, safety, and efficacy of therapeutic products worldwide, with their authority widely acknowledged by drug regulatory agencies across many countries. The FDA's approval of Insulin Glargine Injection has laid a crucial foundation for its accelerated expansion into global markets

About the U.S. Partner:

Founded in 1942, Lannett is a leading manufacturer of pharmaceutical products with a portfolio of over 100 unique pharmaceutical products. The company is headquartered in Trevose, Pennsylvania, USA. The Group has previously entered into a cooperation agreement with Lannett (as a distributor), granting the latter exclusive sales rights in the United States for the Group's two products: insulin glargine and insulin aspart.

This announcement is made by the Company on a voluntary basis to keep investors informed of the latest business development of the Group, and contains no advertisement or intention regarding the use of any drug, surgical device, therapy or oral product.

By order of the Board
Sunshine Lake Pharma Co., Ltd.
Dr. ZHANG Yingjun
Chairman

Dongguan, the PRC

4 May 2026

As at the date of this announcement, the executive Directors are Dr. ZHANG Yingjun and Dr. LI Wenjia, the non-executive Directors are Mr. ZHANG Yushuai, Mr. TANG Xinfa, Mr. ZHU Yingwei, Mr. ZENG Xuebo, Ms. DONG Xiaowei and Ms. WANG Lei, and the independent non-executive Directors are Dr. LI Xintian, Dr. MA Dawei, Dr. YIN Hang Hubert, Dr. LIN Aimei and Dr. YE Tao.