

**Lannett Company, Lanexa Biologics and Sunshine Lake Pharma announce  
FDA Approval of LANGLARA™ an Interchangeable Biosimilar of Lantus® (insulin glargine)**

*This Interchangeable Biosimilar Insulin Glargine Approved for U.S. Distribution  
Through Newly Established Subsidiary Lanexa Biologics LLC*

**PHILADELPHIA – MAY 4, 2026** – Lannett Company, Inc., Lanexa Biologics, a wholly owned subsidiary of Lannett, and Sunshine Lake Pharma today announced that the U.S. Food and Drug Administration (FDA) has approved LANGLARA™ (insulin glargine-aldy), as a biosimilar to Lantus® (insulin glargine), for the treatment of adults and pediatric patients with type 1 diabetes mellitus and adults with type 2 diabetes mellitus. The FDA has determined that LANGLARA is interchangeable with the reference drug, enabling pharmacists to substitute LANGLARA for Lantus without prescriber intervention in states that permit such substitution.

The approval for LANGLARA was based on a comprehensive analytical, preclinical and clinical program which confirmed the PK/PD, efficacy, safety profile and immunogenicity of LANGLARA as compared to Lantus in patients with type 1 and type 2 diabetes.

“Often, the greatest barrier to care for patients living with diabetes is the cost or the availability of the medicine itself. Upon the launch of LANGLARA, supported by the tremendous manufacturing scale of our partner, patients will have expanded access to a safe, affordable and available treatment option. In fact, the scale required to support this medicine is the very reason so few insulin manufacturers exist” stated Tim Crew, CEO of Lannett. “Moreover, earning the interchangeability designation is critical for patient access and reflects the extraordinary quality and scientific rigor of both Lannett and our partner Sunshine Lake Pharma. Lannett and Lanexa Biologics intend to pursue broad formulary placement across all commercial channels, to make this medicine accessible for all who need it.”

LANGLARA is manufactured by Sunshine Lake Pharma Co., Ltd., which is the pharmaceutical business arm of HEC Group and commercialized in the United States exclusively through Lanexa Biologics LLC, a newly formed wholly owned subsidiary of Lannett Company.

“The approval of LANGLARA reflects the significant effort Lannett and Sunshine Lake Pharma invested in bringing affordable insulin to patients in the US. The Sunshine Lake Pharma group has made very substantial investments to support the massive production scale necessary to be a meaningful supplier of this critical medicine,” stated Richard Tang, President of HEC Group. “We are incredibly proud of what this partnership has produced, we look forward to working with Lannett and Lanexa to make this medicine available to patients in the US in the near future.”

**FDA Biosimilar Interchangeability Designation**

An interchangeable biosimilar is a biosimilar that may be substituted for the reference product without the intervention of the prescribing health care provider, depending on state pharmacy laws. Not all biosimilars are interchangeable biosimilars. A manufacturer must specifically seek FDA approval for an interchangeable product.

The approval process for interchangeable biosimilars has additional requirements related to the potential for substitution. Patients receiving their medications through their pharmacies may be able to switch between a brand-name biological product and an interchangeable biosimilar.

### **Strategic Partnership with Sunshine Lake Pharma**

LANGLARA is manufactured by Sunshine Lake Pharma, a leading biopharmaceutical company with world-class biologics manufacturing capabilities and a strong track record of regulatory compliance across international markets. The collaboration between Lannett and Sunshine Lake Pharma reflects a shared commitment to delivering high-quality, affordable biologic medicines to patients who need them. Sunshine Lake Pharma's state-of-the-art manufacturing facility has been designed and operated to meet the exacting standards of both the FDA and international regulatory authorities, providing a robust and scalable supply chain for LANGLARA and future pipeline products. Lannett and Sunshine Lake Pharma also continue to collaborate on a short acting insulin aspart which is in development.

### **About Lanexa Biologics LLC**

Lanexa Biologics LLC is a wholly owned subsidiary of Lannett Company, Inc., established to serve as the commercial platform for Lannett's biosimilar portfolio in the United States. Lanexa combines the distribution infrastructure, payer relationships, and regulatory expertise of its parent company with a dedicated focus on the unique commercial demands of the biologics market. The formation of Lanexa reflects Lannett's long-term commitment to biosimilars as a core growth driver and its belief that purpose-built commercial capabilities are essential to competing effectively in this space. LANGLARA™ is Lanexa's inaugural insulin product. A short acting insulin aspart is also under development.

On July 31, 2025, Aurobindo Pharma announced its intent to acquire Lannett Company, Inc. Upon close of the acquisition, Lanexa will become a stand-alone company.

### **About Lannett Company, Inc.**

Founded in 1942, Lannett Company, Inc. is a leading manufacturer or distributor of about 100 unique pharmaceutical product families that extend and enhance people's lives. Lannett is a US-based company, with headquarters in Trevoze, PA, and top-notch facilities for manufacturing, packaging, and distribution located in Seymour, Indiana.

### **About Sunshine Lake Pharma**

Sunshine Lake Pharma is a multi-billion-dollar China-based pharmaceutical and biotechnology company, and a Hong Kong-listed biopharmaceutical firm under HEC Group (Stock Code: [6887.HK](#)). Driven by independent research and development, the company focuses on key therapeutic areas including pediatric medicines, infectious diseases, chronic diseases and oncology. The company has established integrated capabilities across development and large-scale manufacturing, supporting both domestic and international markets. Through strategic collaborations, including its partnership with Lannett, Sunshine Lake Pharma leverages its technical expertise and production infrastructure to advance complex and biosimilar products. Sunshine Lake Pharma plays a central role in product development and manufacturing execution, supporting global regulatory and commercial efforts.

LANGLARA™ is a registered trademark of Lannett Co.

Lantus® is a registered trademark of Sanofi