信達生物製藥

**INNOVENT BIOLOGICS, INC.**

*(Incorporated in the Cayman Islands with Limited Liability)*

**(Stock Code: 1801)**

# VOLUNTARY ANNOUNCEMENT PECONDLE® (PICANKIBART INJECTION) RECEIVED APPROVAL FROM CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS

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

The board of directors of the Company (the "**Board**") is pleased to announce that the new drug application ("**NDA**") for PECONDLE® (picankibart injection, recombinant anti-interleukin-23p19 subunit ("**IL-23p19**") antibody, R&D code: IBI112) has been approved by the National Medical Products Administration of China ("**NMPA**") for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy. PECONDLE® (picankibart injection) is the first domestically developed IL-23p19 monoclonal antibody approved in China. Among comparable biologics, PECONDLE® (picankibart injection) offers the longest dosing interval during the maintenance period (once every 12 weeks). It is poised to provide Chinese patients with moderate-to-severe plaque psoriasis comprehensive benefits, including significant skin clearance, improved quality of life, and enhanced dosing convenience.

This approval was primarily based on the positive results from the pivotal Phase 3 registrational clinical study CLEAR-1 (NCT05645627) in Chinese subjects with moderate-to-severe plaque psoriasis. The study results showed that:

- At week 16, the proportion of subjects achieving a 90% improvement in the Psoriasis Area and Severity Index ("**PASI 90**") and Static Physician's Global Assessment score of 0 or 1 ("**sPGA 0/1**") in the Picankibart group were 80.3% and 93.5%, respectively, which were significantly higher than those in the placebo group (2.0% and 13.1%, $p < 0.0001$ for both). The proportions of subjects achieving PASI 90 and sPGA 0/1 remained stable at a high level in the Picankibart 100mg and 200mg maintenance treatment groups dosed once every 12 weeks.

- The proportion of participants who achieved PASI 75, PASI 100, sPGA 0, and Dermatology Life Quality Index score of 0 or 1 ("**DLQI 0/1**") was significantly higher in the picankibart group than in the placebo group ($p < 0.0001$), and picankibart showed varying degrees of improvement in psoriasis in special areas (scalp, nail, palmoplantar and perineal);

- The overall safety of picankibart was favorable. The most common adverse events was upper respiratory tract infection, which was consistent with the safety profile of other IL-23p19 agents. No new safety signals were identified.

At present, the number of patients with psoriasis in China exceeds 7 million, among which the number of plaque psoriasis patients is the largest, and the disease is characterized by chronicity and recurrence, often accompanied by itching, pain, scaling and changes in appearance, which significantly affect quality of life and mental health. In addition to skin involvement, patients often experience comorbidities such as cardiometabolic risk (hypertension, dyslipidemia, obesity, abnormal glucose and lipid metabolism, etc.) as well as depression and anxiety, all of which contribute to a long-term medical and economic burden to individuals and society.

In recent years, the treatment of moderate-to-severe plaque psoriasis has evolved from traditional systemic therapies to a new era of precision therapy driven by biological agents and small molecule-targeted drugs. The treatment goal has shifted from achieving a PASI improvement of ≥ 75% (PASI 75) to achieving PASI 90/100, along with a marked improvement in quality of life (DLQI 0-1). At the same time, more attention has been paid to the long-term maintenance and efficacy in special areas (scalp, nail, palmoplantar and perineal).

As the first and backbone drug of the Company's innovative pipeline in the field of autoimmunity, PECONDLE® (picankibart injection) is the world's first IL-23p19 antibody drug whose registrational Phase 3 clinical trial met its primary endpoint with over 80% of subjects achieving PASI 90 at week 16. It also offers the longest maintenance dosing interval (once every 12 weeks) among comparable biologics. PECONDLE® is expected to provide comprehensive benefits, including significant skin clearance, improved quality of life, and enhanced dosing convenience for Chinese patients with moderate-to-severe plaque psoriasis. The Company is devoted to provide a better treatment option for Chinese patients with psoriasis.

**About psoriasis**

Psoriasis is a chronic, recurrent, inflammatory and systemic disease induced by genetic and environmental factors, affecting individuals of all ages and genders. It typically presents as scaly erythema or plaques, with non-infections, localized or widespread distribution. As a life-long noninfectious condition, psoriasis is notoriously difficult to treat. The disease can be categorized into psoriasis vulgaris (including guttate psoriasis and plaque psoriasis), pustular psoriasis, erythrodermic psoriasis and arthropathic psoriasis. Approximately 80%-90% of patients have plaque psoriasis, with nearly 30% of the cases being moderate to severe. Global psoriasis prevalence varies significantly, with over 7 million patients in China alone. Current systemic treatments in China include methotrexate (MTX), cyclosporine A, retinoic acids and biological agents. Since 2019, biologics have become a central focus in psoriasis treatment in China, with IL-23 inhibitors distinguished by their target precision, rapid onset, robust efficacy, favorable safety profile, and durable effects. These agents offer significant advantages in achieving comprehensive and deep lesion clearance, as well as in prolonging relapse-free periods.

**About PECONDLE® (Picankibart injection)**

Picankibart (R&D code: IBI112) is a monoclonal antibody independently developed by Innovent with proprietary intellectual property rights. This product specifically targets the IL-23p19 subunit, preventing IL-23 from binding to cell surface receptors. Picankibart has the potential to offer a more effective treatment option with longer dosing intervals for patients with psoriasis, ulcerative colitis or other autoimmune diseases.

PECONDLE® (picankibart injection) is approved by the NMPA for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.

Currently, multiple clinical studies of picankibart are underway, including:

- CLEAR-1: A Phase 3 clinical study in patients with moderate-to-severe plaque psoriasis;
- CLEAR-2: A Phase 3 clinical study in patients with moderate-to-severe plaque psoriasis with randomized withdrawal and re-treatment;
- CLEAR-3: A Phase 3 clinical study (CLEAR-3) in patients with moderate to severe plaque psoriasis who were previously treated with biologics;
- A Phase 2 clinical study in patients with moderate to severe plaque psoriasis who were previously treated with biologics; and
- A Phase 2 clinical study in patients with moderately to severely active ulcerative colitis.

Except for the ongoing CLEAR-3 study, all other studies have met their primary endpoints.

In addition, new clinical studies of picankibart in the treatment of adolescent psoriasis and adult psoriatic arthritis are initiated.

By Order of the Board
**Innovent Biologics, Inc.**
**Dr. De-Chao Michael Yu**
*Chairman and Executive Director*

Hong Kong, China
November 28, 2025

*As at the date of this announcement, the Board comprises Dr. De-Chao Michael Yu as Chairman and executive Director and Mr. Ronald Hao Xi Ede and Ms. Qian Zhang as executive Directors, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Mr. Gary Zieziula, Dr. Shun Lu, Mr. Shuyun Chen and Dr. Stephen A. Sherwin as independent non-executive Directors.*