信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT
INNOVENT AND LG CHEM ANNOUNCE STRATEGIC COLLABORATION FOR TIGULIXOSTAT, A NOVEL NON-PURINE XANTHINE OXIDASE INHIBITOR FOR THE TREATMENT OF GOUT DISEASE

This announcement is made by Innovent Biologics, 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 updates of the Group.

The board of directors of the Company (the "**Board**") is pleased to announce that and the Group and LG Chem Life Sciences (the "**LG Chem**"), a division of LG Chem, have entered into a strategic collaboration and license agreement (the "**Agreement**") regarding LG Chem's Tigulixostat (LG R&D code: LC350189, Innovent R&D code: IBI-350), a late-stage novel non-purine xanthine oxidase inhibitor (the "**XOI**") for the chronic management of hyperuricemia in patients with gout disease.

Under the Agreement, the Group will obtain an exclusive right to develop and commercialize Tigulixostat in China. LG Chem will receive totaling up to US$95.5 million for the China rights including US$10 million upfront payment, milestone payments, plus tiered royalties on the annual net sales of the product in China.

Hyperuricemia is one of the most prevailing chronic diseases globally with a huge patient population. Prevalence rate of hyperuricemia is as high as approximately 13.3% (approximately 187 million people) in China. Moreover, hyperuricemia is the predisposing condition for gout, and the number of hyperuricemia patients with gout symptoms is up to approximately 15.5 million in China. Febuxostat and Allopurinol as XOI inhibitors, are current therapies recommended for the treatment of hyperuricemia including gout, but contains clear limitations: Febuxostat has potential cardiovascular risks and Allopurinol could cause high incidence of hypersensitivity in Asian population. Under these circumstances, there exists a huge unmet medical need for the treatment of hyperuricemia.

In the Phase 2 study conducted in the United States ("**U.S.**") (CLUE Study), Tigulixostat showed serum uric acid (the "**sUA**")-lowering effects across all dose levels, and achieved a treatment target of sUA<5mg/dL as the primary endpoint at month 3 with all dose groups when compared with placebo, and Febuxostat. LG Chem has initiated multi-regional global Phase 3 clinical trials for Tigulixostat in the fourth quarter of 2022. As hyperuricemia and gout is both a rheumatic disease and a metabolic disease, the collaboration fits into the Group's strategic planning in rheumatic and metabolic areas, as well as creates great synergy with current pipeline, development resources and commercial network. Based on the huge unmet medical need and solid clinical data, the Group hopes to bring the next-generation XOI drug to the market as quickly as possible and benefit the patients in China.

About Tigulixostat (LC350189, IBI350)

Tigulixostat is a novel XOI targeting the reduction of uric acid in the final product in purine metabolism, by inhibiting the activity of xanthine oxidase. It has a different structure from other XOIs such as the purine analog XOI, allopurinol. Tigulixostat is under development as a 1st line treatment in the U.S. and has demonstrated sufficient efficacy for sUA lowering and a good safety profile in a Phase 2 study.

About CLUE study

LG Chem had received The U.S. Food and Drug Administration clearance to commence a Phase 2 trial of Tigulixostat in June 2019 and conducted the Phase 2 study (CLUE study, NCT03934099) with 156 gout patients at 42 clinical sites in the US.

Participants with chronic gout, defined as hyperuricemia and a history or presence of gout according to ACR criteria and baseline sUA levels ≥ 8 mg/dL, ≤12 mg/dL were administered Tigulixostat (50, 100, and 200 mg) or placebo orally, once daily for 3 months, with a subset of 13 out of 156 participants enrolled in a Febuxostat, 40 mg to 80 mg QD, active control group.

During the study period, colchicine 0.6 mg (QD) was prescribed to the patients for prophylaxis of gout flares. The primary endpoint was the response rate achieving sUA < 5 mg/dL at month 3.

Topline results from the CLUE study are as follows:

- The proportion of gout patients reaching sUA < 5 mg/dL at month 3 by study arms was 47% (16/34) at 50 mg, 45% (17/38) at 100 mg, 62% (23/37) at 200 mg Tigulixostat, respectively, 23% (3/13) with Febuxostat and 3% (1/34) with placebo.

- The proportion of patients achieving sUA < 6 mg/dL at month 3 as the secondary endpoint was 59%, 63%, and 78% at 50, 100, and 200 mg of Tigulixostat, respectively, 54% in the Febuxostat group, and 3% in the placebo group.

- Tigulixostat showed good dose-dependent reduction in sUA levels lowering rapidly within 2 weeks, and sUA levels were well maintained throughout the study period.

- Tigulixostat was well tolerated in gout patients at all dose levels compared to the placebo group. There was no notable difference in the overall incidence of TEAE (treatment-emergent adverse events) between the active Tigulixostat and placebo groups.

Forward-Looking Statements

This announcement may contain certain forward-looking statements that are, by their nature, subject to significant risks and uncertainties. The words "anticipate", "believe", "estimate", "expect", "intend" and similar expressions, as they relate to the Company, are intended to identify certain of such forward-looking statements. The Company does not intend to update these forward-looking statements regularly.

These forward-looking statements are based on the existing beliefs, assumptions, expectations, estimates, projections and understandings of the management of the Company with respect to future events at the time these statements are made. These statements are not a guarantee of future developments and are subject to risks, uncertainties and other factors, some of which are beyond the Company's control and are difficult to predict. Consequently, actual results may differ materially from information contained in the forward-looking statements as a result of future changes or developments in our business, the Company's competitive environment and political, economic, legal and social conditions.

The Company, the Directors and the employees of the Company assume (a) no obligation to correct or update the forward-looking statements contained in this site; and (b) no liability in the event that any of the forward-looking statements does not materialise or turn out to be incorrect.

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

Hong Kong, China
December 15, 2022

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 as Executive Director, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen and Mr. Gary Zieziula as Independent Non-executive Directors.