信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT

SINTILIMAB IN COMBINATION WITH CHEMOTHERAPY MEETS PRIMARY ENDPOINT IN THE GLOBAL PHASE 3 ORIENT-15 STUDY FOR THE FIRST-LINE TREATMENT OF ESOPHAGEAL SQUAMOUS CELL CARCINOMA

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 the Phase 3 ORIENT-15 study met the predefined overall survival ("**OS**") primary endpoint. ORIENT-15 is a global randomized, double-blind, multi-center clinical study evaluating sintilimab in combination with chemotherapy (cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil ("**5-FU**")) for the first-line treatment of patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma ("**ESCC**").

Based on an interim analysis conducted by the Independent Data Monitoring Committee, sintilimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of OS compared to placebo in combination with chemotherapy, regardless of PD-L1 expression status. The safety profile of sintilimab in this study was consistent with that observed in previously reported studies of sintilimab, and no additional safety signals were identified. These ORIENT-15 results will be presented at an upcoming medical conference.

Esophageal cancer is the seventh most commonly diagnosed cancer and the sixth leading cause of death from cancer worldwide. Based on the data from GLOBOCAN 2020, it is estimated that there were approximately 600,000 new cases of esophageal cancer diagnosed and approximately 540,000 deaths resulting from the disease worldwide in 2020. More than half of new and fatal cases of esophageal cancer in the world occur in China, with approximately 320,000 new cases diagnosed and approximately 300,000 deaths resulting from the disease in 2020. 5-year survival rate of esophageal cancer is merely 30% in China. In the recent years, immunotherapy brings new hope of treatment in ESCC. The Company is pleased that results of ORIENT-15 study proves that sintilimab in combination with chemotherapy can prolong OS in the first-line treatment of ESCC, which could bring hope to more patients.

About ORIENT-15 Study

ORIENT-15 is a global randomized, double-blind, multi-center Phase 3 clinical study evaluating sintilimab in combination with chemotherapy compared to placebo in combination with chemotherapy, for the first-line treatment of unresectable locally advanced, recurrent or metastatic ESCC (ClinicalTrials.gov, NCT03748134). At the time of interim analysis, a total of 659 eligible patients were enrolled and randomly assigned into the experimental group or control group in a 1:1 ratio. Patients were enrolled regardless of PD-L1 status. The primary endpoints are OS in all randomized patients and overall survival in the PD-L1 positive (CPS ≥10) patients.

About Sintilimab

Sintilimab, marketed TYVYT® (sintilimab injection) in China, is an innovative PD-1 inhibitor with global quality standards jointly developed by the Company and Lilly. Sintilimab is a type of immunoglobulin G4 monoclonal antibody, which binds to PD-1 molecules on the surface of T-cells, blocks the PD-1/PD-L1 pathway, and reactivates T-cells to kill cancer cells. The Company is currently conducting more than 20 clinical studies of sintilimab to evaluate its safety and efficacy in a wide variety of cancer indications, including more than 10 registrational or pivotal clinical trials.

In China, sintilimab has been approved for three indications, including:

- The treatment of relapsed or refractory classic Hodgkin's lymphoma after two lines or later of systemic chemotherapy

- In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of nonsquamous non-small cell lung cancer ("**NSCLC**")

- In combination with gemcitabine and platinum chemotherapy, for the first-line treatment of squamous NSCLC

Additionally, the Company currently has regulatory submissions under review by National Medical Products Administration in China for sintilimab:

- In combination with BYVASDA® (bevacizumab injection) for the first-line treatment of hepatocellular carcinoma

- The second-line treatment of squamous NSCLC

The Company also has two clinical studies that have met primary endpoint for sintilimab:

- In combination with cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil for the first-line treatment of esophageal squamous cell carcinoma

- The second-line treatment for esophageal squamous cell carcinoma

In May 2021, the U.S. FDA accepted for review the Biologics License Application for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of nonsquamous NSCLC.

Sintilimab was included in China's National Reimbursement Drug List in November 2019 as the first PD-1 inhibitor and the only PD-1 included in the list in that year.

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
June 23, 2021

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