信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT
THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION ACCEPTED THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TYVYT® (SINTILIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY AS FIRST-LINE THERAPY FOR 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 National Medical Products Administration (the "**NMPA**") has accepted the supplemental New Drug Application ("**sNDA**") for TYVYT® (sintilimab injection) in combination with chemotherapy (cisplatin plus paclitaxel/cisplatin plus 5-fluorouracil) for the first-line treatment of esophageal squamous cell carcinoma ("**ESCC**").

The sNDA application is based on the interim analysis of the global randomized, double-blind, multi-center Phase 3 ORIENT-15 clinical trial – which evaluated sintilimab in combination with chemotherapy compared to placebo in combination with chemotherapy as first-line therapy for ESCC. Based on the interim analysis conducted by the Independent Data Monitoring Committee ("**IDMC**"), sintilimab in combination with chemotherapy demonstrated a significant improvement in the primary endpoint of overall survival ("**OS**") of patients 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. The results of ORIENT-15 were presented at the European Society for Medical Oncology Congress 2021.

Esophageal cancer is the fifth most commonly diagnosed cancer and the fourth leading cause of death from cancer in China, and squamous cell carcinoma is the predominant histologic type. There is a huge unmet clinical need for the first-line treatment of advanced or metastatic ESCC given the limited OS benefit of chemotherapy treatment. The results of ORIENT-15 demonstrated that sintilimab plus chemotherapy (cisplatin plus paclitaxel/cisplatin plus 5-fluorouracil) significantly improved OS and progression-free survival compared to chemotherapy. The Company hopes to bring the new regimen to Chinese patients with ESCC as quickly as possible.

About the ORIENT-15 Study

ORIENT-15 is a global randomized, double-blind, multicenter Phase 3 clinical study evaluating sintilimab in combination with chemotherapy (cisplatin plus paclitaxel/cisplatin plus 5-fluorouracil), compared to placebo in combination with chemotherapy (cisplatin plus paclitaxel/cisplatin plus 5-fluorouracil), 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. The primary endpoints were OS in all randomized patients and OS in PD-L1 positive (defined as CPS ≥10) patients.

About Sintilimab

Sintilimab, marketed as TYVYT® (sintilimab injection) in China, is an innovative PD-1 inhibitor with global quality standards jointly developed by the Company and Eli Lilly and Company. Sintilimab is an immunoglobulin G4 monoclonal antibody, which binds to PD-1 molecules on the surface of T-cells, blocks the PD-1/PD-Ligand 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 four 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 non-squamous non-small cell lung cancer ("**NSCLC**")

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

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

Additionally, the Company currently has two regulatory submissions under review by NMPA for sintilimab, for the first-line treatment of ESCC and the second-line treatment of squamous NSCLC.

The Company also has additional two clinical studies of sintilimab that have met their primary endpoints:

- Phase 3 clinical study in combination with oxaliplatin and capecitabine for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma

- Phase 2 clinical study of the second-line treatment of ESCC

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

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

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

Hong Kong, China,
September 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.