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 APPROVES THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TYVYT® (SINTILIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY AS FIRST-LINE TREATMENT FOR ADVANCED OR METASTATIC GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA

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 ("**NMPA**") of China has approved the supplemental New Drug Application ("**sNDA**") for innovative PD-1 inhibitor TYVYT® (sintilimab injection) in combination with fluorouracil and platinum-based chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma.

The approval is based on the results of a randomized, double-blind, multicenter Phase 3 clinical trial (ORIENT-16) evaluating sintilimab in combination with chemotherapy (oxaliplatin and capecitabine), compared to placebo in combination with chemotherapy, for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma. Based on the interim analysis by Independent Data Monitoring Committee (iDMC), sintilimab in combination with chemotherapy demonstrated superior overall survival ("**OS**"), compared to placebo plus chemotherapy, with a 34.0% reduction in the risk of death (HR 0.660, 95%CI 0.505-0.864, p=0.0023) and a 5.5-month improvement in median OS ("**mOS**", 18.4 months vs. 12.9 months) in patients with combined positive score (CPS) ≥5, and 23.4% reduction in the risk of death (HR 0.766, 95%CI 0.626-0.936, p=0.0090) and a 2.9-month improvement in mOS (15.2 months vs. 12.3 months) in all patients regardless of PD-L1 expression. 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 for the combination of sintilimab and chemotherapy. The results of ORIENT-16 study were presented at the European Society for Medical Oncology ("**ESMO**") Congress 2021.

Gastric cancer is one of the most common malignant tumor types worldwide. According to GLOBOCAN 2020 estimates, there were approximately one million new cases in 2020 and 769,000 new deaths of gastric cancer each year, making it the fifth most common cancer and third leading cause of cancer death globally. About half of all gastric cancer cases occurred in East Asia, mainly in China. The first-line treatment of advanced gastric cancer is still limited. Currently, the 5-year survival rate of advanced or metastatic gastric cancer ranges from 5% to 20%. The mOS was about 1 year for patients who received chemotherapy only.

The results of ORIENT-16 demonstrated significant improvement in OS in patients with advanced gastric cancer and safety profile was consistent with that observed in previously reported studies of sintilimab. Survival benefit and reduction in the risk of death were observed, regardless of PD-L1 expression. This sNDA approval enables TYVYT® (sintilimab injection) to be the domestically first innovative PD-1 inhibitor for the first-line treatment of five major type of cancers. The Company believes that the approval of this new indication will further strengthen the leadership position of TYVYT® (sintilimab injection) in PD-1 market in China and bring safe and efficacious treatment options to more cancer patients.

About ORIENT-16 Study

ORIENT-16 is a randomized, double-blind, multi-center Phase 3 clinical study evaluating sintilimab or placebo, in combination with chemotherapy (oxaliplatin and capecitabine), for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma (ClinicalTrials.gov, NCT03745170). The primary endpoint was OS in PD-L1 positive (CPS>5) and all randomized patients.

As of the cutoff date for the interim analysis, a total of 650 patients were enrolled and randomly assigned with a 1:1 ratio to receive sintilimab or placebo in combination with chemotherapy until disease progression, unacceptable toxicity, withdrawal of consent, or death, whichever occurs first. The study met both primary endpoints and 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 for the combination of sintilimab and chemotherapy. The results were published at the ESMO Congress 2021.

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 of various solid tumors and hematological tumor, including more than 10 registrational or pivotal clinical trials.

In China, sintilimab has been approved for six indications as below, with the first four included in the National Reimbursement Drug List, including:

- The treatment of relapsed or refractory classic Hodgkin's lymphoma after at least 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**") lacking EGFR or ALK driver mutations;

- 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 unresectable or advanced hepatocellular carcinoma;

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

- In combination with fluorouracil and platinum-based for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma.

The Company currently has the regulatory submission for sintilimab in combination with bevacizumab biosimilar and chemotherapy for EGFR-mutated non-squamous NSCLC following EGFR-TKI treatment under review by the NMPA.

Additionally, two clinical studies of sintilimab have met their primary endpoints:

- Phase 2 study as second-line treatment of esophageal squamous cell carcinoma;

- Phase 3 study as second-line treatment for squamous NSCLC with disease progression following platinum-based chemotherapy.

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

Hong Kong, China,
June 24, 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.