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 TREATMENT 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 ("**NMPA**") of China has accepted the supplemental New Drug Application ("**sNDA**") for innovative PD-1 inhibitor TYVYT® (sintilimab injection) in combination with cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic esophageal squamous cell carcinoma ("**ESCC**").

The acceptance of sNDA is based on the interim analysis of ORIENT-15, a global randomized, double-blind, multi-center Phase III 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 statistically significant improvement in the primary endpoint of overall survival ("**OS**") compared to placebo in combination with chemotherapy regardless of PD-L1 expression status, meeting the pre-defined superior efficacy criteria. Safety profile was consistent with that observed in previously reported studies of sintilimab without new or unexpected safety signals. The results of ORIENT-15 were published in *British* Medical Journal on April 19, 2022.

Esophageal cancer is one of the most common malignant tumors worldwide that begins in the inner layer (mucosa) of the esophagus, which connects the throat to the stomach. Based on GLOBOCAN 2020 estimates, approximately 600,000 new cases of EC are diagnosed and approximately 540,000 deaths result from the disease worldwide each year. EC is the seventh most commonly diagnosed cancer and the sixth leading cause of death from cancer worldwide. More than half of new and fatal cases of EC in the world occur in China. In China, it is estimated that there were approximately 320,000 new cases of esophageal cancer diagnosed and approximately 300,000 deaths resulting from the disease in 2020. EC is the fifth most commonly diagnosed cancer and the fourth leading cause of death from cancer in China, where it has a five-year survival rate of only 30%.

The two main types of EC are squamous cell carcinoma ("**SCC**") and adenocarcinoma. In China, SCC is the predominant histologic type, accounting for more than 90% of all EC. In the past, first-line standard systemic therapy was chemotherapy based on platinum drugs for unresectable locally advanced, recurrent or metastatic ESCC, which calls for more effective first-line treatment options as the median overall survival has been less than one year.

The results of ORIENT-15 demonstrated that sintilimab can bring significant clinical benefit to the treatment of ESCC. The Company will work with regulatory authorities on the sNDA review and believe that the approval of this new indication will further strengthen the leadership position of TYVYT® (sintilimab injection) and bring hopes to more Chinese cancer patients in broader market.

**About 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 or 5-fluorouracil 5-FU), 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 (of the planned 676 estimated participants) were enrolled and randomly assigned into the experimental group or control group in a 1:1 ratio. The primary endpoints were overall survival in all randomized patients and OS in PD-L1 positive (defined as CPS ≥10) patients.

Based on the interim analysis conducted by the Independent Data Monitoring Committee (iDMC), sintilimab in combination with chemotherapy demonstrated a statistically significant improvement in the primary endpoint of OS compared to placebo in combination with chemotherapy, regardless of PD-L1 expression status, meeting the pre-defined superior efficacy criteria. Safety analysis revealed no new safety signals. The results of ORIENT-15 were published in *British* Medical Journal on April 19, 2022.

**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 and included in the National Reimbursement Drug List ("**NRDL**") for four indications, and recently approved for one additional indication 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 lacking EGFR or ALK driver mutations;
- In combination with gemcitabine and platinum chemotherapy, for the first-line treatment of squamous non-small cell lung cancer;
- In combination with BYVASDA® (bevacizumab biosimilar injection) for the first-line treatment of unresectable or advanced hepatocellular carcinoma; and
- In combination with cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil for the first-line treatment of ESCC.

Additionally, the Company currently has two regulatory submissions under review in the China's NMPA for sintilimab:

- In combination with chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma; and
- In combination with bevacizumab biosimilar and chemotherapy for EGFR-mutated non-squamous NSCLC following EGFR-TKI treatment.

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

- Phase 2 study as second-line treatment of ESCC; and
- 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 20, 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.*