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 GRANTED CONDITIONAL APPROVAL FOR TYVYT® (SINTILIMAB INJECTION) IN COMBINATION WITH ELUNATE® (FRUQUINTINIB) FOR THE TREATMENT OF ADVANCED ENDOMETRIAL CANCER

This announcement is made by Innovent Biologics, Inc. (the "**Company**" or "**Innovent**", 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 new drug application ("**NDA**") for the combination of TYVYT® (sintilimab injection) and ELUNATE® (fruquintinib) has been granted conditional approval in China for the treatment of patients with advanced endometrial cancer ("**EMC**") with Mismatch Repair proficient ("**pMMR**") tumors that have failed prior systemic therapy and are not candidates for curative surgery or radiation. This approval follows the priority review status and breakthrough therapy designation by the National Medical Products Administration ("**NMPA**") of China.

The conditional approval by the NMPA was supported by registration stage data from FRUSICA-1, the EMC registration cohort of a multi-center, open-label Phase 2 clinical study investigating sintilimab in combination with fruquintinib in EMC patients who have experienced disease recurrence, disease progression or intolerable toxicity with treatment on platinum-based doublet chemotherapy. Results from FRUSICA-1 were presented at the American Society of Clinical Oncology annual meeting in June 2024.[i] The study results showed that independent review committee (IRC)-assessed objective response rate (ORR) and disease control rate (DCR) was 35.6% and 88.5% respectively; The combination treatment showed rapid on-set efficacy, with a median time to tumor response (mTTR) of only 1.6 months. The median progression free survival (PFS) and overall survival (OS) reached 9.5 months and 21.3 months respectively. Adverse events are consistent with those reported for similar immunotherapy and antiangiogenic agents combination treatments. Additional details can be found at clinicaltrials.gov, using identifier NCT03903705. A Phase 3 confirmatory study of the sintilimab and fruquintinib combination in this setting has been planned (NCT06584032).

This approval marks the eighth approved indication for TYVYT® (sintilimab injection) to benefit broader cancer patients. Together with our partner HUTCHMED (Nasdaq/AIM: HCM; HKEX: 13), the Company aims to provide a novel treatment option that improves survival rates and quality of life for patients facing limited treatment options against this aggressive cancer. TYVYT® (sintilimab injection), as a cornerstone in immuno-therapy, continues to be evaluated in clinical trials in combination with novel modalities. We remain steadfast in our commitment to reinforcing the leadership position of TYVYT® (sintilimab injection) in immuno-therapy and driving forward treatment solutions through innovation and cooperation.

About Endometrial Cancer

EMC originates in the uterus and remains a significant global health challenge. In 2020, approximately 417,000 people worldwide were diagnosed with EMC, resulting in around 97,000 deaths.[ii] In China alone, an estimated 82,000 new cases and 17,000 deaths were reported that year.[iii] While early-stage cases can often be surgically resected, recurrent and/or metastatic EMC remains an area of high unmet need with poor outcomes and limited treatment options.[iv, v, vi]

About Sintilimab

Sintilimab, marketed as TYVYT® (sintilimab injection) in China, is a programmed cell death protein 1 ("**PD-1**") immunoglobulin G4 monoclonal antibody co-developed by Innovent and Eli Lilly and Company. 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-Ligand 1 (PD-L1) pathway, and reactivates T-cells to kill cancer cells.[vii]

In China, sintilimab has been approved and included in the updated National Reimbursement Drug List ("**NRDL**") for seven indications. The updated NRDL reimbursement scope for TYVYT® (sintilimab injection) includes:

- For the treatment of relapsed or refractory classic Hodgkin's lymphoma after two lines or later of systemic chemotherapy;
- For the first-line treatment of unresectable locally advanced or metastatic non-squamous non-small cell lung cancer ("**NSCLC**") lacking epidermal growth factor receptor ("**EGFR**") or anaplastic lymphoma kinase (ALK) driver gene mutations;
- For the treatment of patients with EGFR-mutated locally advanced or metastatic non-squamous NSCLC who progressed after EGFR-tyrosine kinase inhibitors therapy;
- For the first-line treatment of unresectable locally advanced or metastatic squamous NSCLC;
- For the first-line treatment of unresectable or metastatic hepatocellular carcinoma with no prior systematic treatment;
- For the first-line treatment of unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma ("**ESCC**"); and
- For the first-line treatment of unresectable locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma.

Furthermore, sintilimab's eighth indication, in combination with fruquintinib for the treatment of patients with advanced EMC with pMMR tumors that have failed prior systemic therapy and are not candidates for curative surgery or radiation, was approved by the NMPA in December 2024.

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

- Phase 2 study of sintilimab monotherapy as second-line treatment of ESCC; and

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

About Fruquintinib

Fruquintinib is a selective oral inhibitor of all three vascular endothelial growth factor ("**VEGF**") receptors (VEGFR-1, -2 and -3). VEGFR inhibitors play a pivotal role in inhibiting tumor angiogenesis. Fruquintinib was designed to have enhanced selectivity that limits off-target kinase activity, allowing for drug exposure that achieves sustained target inhibition and flexibility for potential use as part of a combination therapy.

Fruquintinib is approved for marketing for the treatment of patients with metastatic colorectal cancer who have previously received fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, and those who have previously received or are not suitable for receiving anti-VEGF therapy or anti-EGFR therapy (RAS wild-type) in China, where it is co-developed and co-marketed by HUTCHMED and Eli Lilly and Company under the brand name ELUNATE®. It was included in the China NRDL in January 2020. Since its launch in China, over 100,000 patients with colorectal cancer have been treated with fruquintinib.

In December 2024, fruquintinib was approved by NMPA in combination with sintilimab for the treatment of patients with advanced EMC with pMMR tumors that have failed prior systemic therapy and are not candidates for curative surgery or radiation.

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

Hong Kong, China,
December 3, 2024

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

References

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[ii] The Global Cancer Observatory, World Fact Sheet. Accessed June 12, 2023.

[iii] The Global Cancer Observatory, China Fact Sheet. Accessed June 12, 2023.

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[v] Koppikar S, et al. Pan-Asian adapted ESMO Clinical Practice Guidelines for the diagnosis, treatment and follow-up of patients with endometrial cancer. *ESMO Open*. 2023; 8(1): 100774. DOI: 10.1016/j.esmoop.2022.100774.

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[vii] Wang J, et al. Durable blockade of PD-1 signaling links preclinical efficacy of sintilimab to its clinical benefit. *mAbs* 2019; 11(8): 1443-1451. DOI: 10.1080/19420862.2019.1654303.