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 NEW DRUG APPLICATION AND GRANTED PRIORITY REVIEW DESIGNATION FOR SINTILIMAB COMBINATION WITH 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 National Medical Products Administration ("**NMPA**") of China has accepted the New Drug Application ("**NDA**") and granted priority review designation for the combination of sintilimab and fruquintinib for the treatment of patients with advanced endometrial cancer ("**EMC**") with Mismatch Repair proficient ("**pMMR**") or non-Microsatellite instability-high ("**non-MSI-H**") tumors that have failed prior systemic therapy but are not candidates for curative surgery or radiation.

The NDA is supported by 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 experienced disease recurrence, disease progression or intolerable toxicity with treatment on platinum-based doublet chemotherapy. The primary endpoint was independent review committee (IRC) assessed objective response rate (ORR), with secondary endpoints including disease control rate (DCR), duration of response (DoR), progression free survival (PFS), overall survival (OS), as well as pharmacokinetic (PK) assessments. Data from FRUSICA-1 will be submitted for presentation at an upcoming medical conference. Additional details may be found at clinicaltrials.gov, using identifier NCT03903705.

EMC is a type of cancer that begins in the uterus. Globally, an estimated 417,000 people were diagnosed with EMC, causing approximately 97,000 deaths in 2020[i]. In China, an estimated 82,000 people were diagnosed with EMC, causing approximately 17,000 deaths in 2020[ii]. Although early-stage EMC can be surgically resected, recurrent and/or metastatic EMC remains an area of high unmet need with poor outcomes and limited treatment options[iii, iv, v].

TYVYT® (sintilimab injection), as a backbone therapy in immuno-oncology, in combination with an anti-angiogenetic drug, may improve the prognosis for EMC patients in China. The Company is pleased with the NDA acceptance and priority review designation, which increases the potential to bring a new treatment option to EMC patients and will concurrently strengthen the leadership position of TYVYT® (sintilimab injection) in China.

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[vi].

In China, sintilimab has been approved and included in the 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-TKI (tyrosine kinase inhibitor) 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; and
- For the first-line treatment of unresectable locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma.

Besides, the combination of sintilimab and fruquintinib for the treatment of patients with advanced endometrial cancer with pMMR or non-MSI-H tumors that have failed prior systemic therapy but are not candidates for curative surgery or radiation has been accepted and granted priority review by the NMPA.

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

- Phase 2 clinical study of sintilimab monotherapy as second-line treatment of esophageal squamous cell carcinoma; and
- Phase 3 clinical study of sintilimab monotherapy as second-line treatment for squamous NSCLC with disease progression following platinum-based chemotherapy.

Statement: The Company does not recommend the use of any unapproved drug(s)/indication(s).

About Fruquintinib

Fruquintinib is a selective oral inhibitor of vascular endothelial growth factor receptor ("**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 high drug exposure, sustained target inhibition and flexibility for its potential use as part of a combination therapy. Fruquintinib has demonstrated a manageable safety profile and is being investigated in combinations with other anti-cancer therapies.

About Fruquintinib Approval in China

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-vascular endothelial growth factor ("VEGF") therapy or anti-epidermal growth factor receptor ("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 NRDL in January 2020. The approval was based on data from the FRESCO study, a Phase 3 pivotal registration trial of fruquintinib in 416 patients with metastatic colorectal cancer in China, which were published in *The Journal of the American Medical Association (JAMA)*. Since its launch in China and as of mid-2023, fruquintinib has benefited more than 80,000 colorectal cancer patients.

About Fruquintinib Approval in the United States

Fruquintinib received approval for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy in the United States in November 2023, where it is marketed by Takeda under the brand name FRUZAQLA™. The approval was based on data from two large Phase 3 trials: the multi-regional FRESCO-2 trial, data from which were published in *The Lancet*, along with the FRESCO trial conducted in China. The trials investigated fruquintinib plus best supportive care versus placebo plus best supportive care in patients with previously treated metastatic colorectal cancer. Both FRESCO and FRESCO-2 met their primary and key secondary efficacy endpoints and showed consistent benefit among a total of 734 patients treated with fruquintinib. Safety profiles were consistent across trials. Takeda has the exclusive worldwide license to further develop, commercialize, and manufacture fruquintinib outside of mainland China, Hong Kong and Macau.

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

Hong Kong, China,
April 2, 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 as Executive Director, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen, Mr. Gary Zieziula and Dr. Shun Lu as Independent Non-executive Directors.

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

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

[iii] Yi A, et al. Real-world characteristics and treatment pattern of patients with newly diagnosed endometrial cancer in China. J Clin Oncol. 2023;41, no. 16_suppl (June 01, 2023) e17613-e17613. DOI: 10.1200/JCO.2023.41.16_suppl.e17613.

[iv] 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.

[v] Siegel RL, et al. Cancer statistics, 2023. CA Cancer J Clin. 2023;73(1):17-48. DOI:10.3322/caac.21763.

[vi] Wang J, Fei K, Jing H, 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.