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 FOR SINTILIMAB COMBINATION WITH FRUQUINTINIB FOR THE TREATMENT OF ADVANCED RENAL CELL CARCINOMA

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**") for the combination of sintilimab and fruquintinib for the treatment of patients with locally advanced or metastatic renal cell carcinoma ("**RCC**") who have failed prior treatment with one tyrosine kinase inhibitor ("**TKI**").

The NDA is supported by data from FRUSICA-2, a randomized, open-label, active-controlled registration study evaluating the efficacy and safety of sintilimab in combination with fruquintinib versus axitinib or everolimus monotherapy for the second-line treatment of advanced RCC. The study has met its primary endpoint of progression free survival ("**PFS**"), as assessed by blinded independent central review (BICR) according to RECIST 1.1 criteria. The combination treatment also demonstrated improvements in secondary endpoints including objective response rate ("**ORR**") and duration of response ("**DoR**"). The safety profile was tolerable and no new safety signals were observed. Data from FRUSICA-2 will be submitted for presentation at an upcoming scientific conference. Additional details may be found at clinicaltrials.gov, using identifier NCT05522231.

It is estimated that approximately 435,000 new patients were diagnosed with kidney cancer worldwide in 2022.[i] In China, an estimation of 74,000 new patients were diagnosed with kidney cancer in 2022.[ii] Approximately 90% of kidney tumors are RCC. Single-agent targeted therapy continues to be one of the primary choices for first-line treatment of advanced RCC in China. Notably, advanced RCC patients who have experienced failure with single-agent targeted therapy previously still indicate an unmet medical need.

TYVYT® (sintilimab injection), as a backbone therapy in immuno-oncology ("**IO**"), in combination with fruquintinib, may represent a significant step toward providing a more effective treatment option for patients with second-line advanced RCC in China. The Company is pleased with the NDA acceptance, which is the 10th NDA for TYVYT® (sintilimab injection), further consolidating its leading position as a cornerstone of IO therapy. It is also an important milestone in the lifecycle management and clinical value optimization for TYVYT® (sintilimab injection).

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 and co-commercialized by Innovent and Eli Lilly, 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.[iii]

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-TKI 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.

Furthermore, sintilimab's eighth indication, in combination with fruquintinib for the treatment of patients with advanced endometrial cancer with proficient mismatch repair ("**pMMR**") tumors that have failed prior systemic therapy and are not candidates for curative surgery or radiation, was conditional approved by the NMPA in December 2024.

Two NDAs for sintilimab are currently under the NMPA review, including:

- In combination with ipilimumab as neoadjuvant treatment for resectable microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) colon cancer is under the NMPA review and has been granted Priority Review designation; and

- In combination with fruquintinib for the treatment of patients with locally advanced or metastatic RCC who failed prior treatment with one TKI.

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;

- Phase 3 clinical 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 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.[iv]

About Fruquintinib Approvals

Fruquintinib is co-developed and co-commercialized in China by HUTCHMED and Eli Lilly and Company under the brand name ELUNATE®. It is approved 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 to receive anti-VEGF therapy or anti – EGFR therapy (RAS wild-type) in China. It was included in the NRDL in January 2020. Since its launch in China, over 100,000 patients with colorectal cancer have been treated with fruquintinib.

The combination of ELUNATE® (fruquintinib) and TYVYT® (sintilimab injection) has conditional approval in China for the treatment of patients with advanced pMMR endometrial cancer who have failed prior systemic therapy and are not candidates for curative surgery or radiation.

Takeda holds the exclusive worldwide license to further develop, commercialize, and manufacture fruquintinib outside China, Hong Kong and Macau, marketing it under the brand name FRUZAQLA®. Fruquintinib received approval for the treatment of previously treated metastatic colorectal cancer in the US, Europe, Japan and many other countries around the world.

The safety and efficacy of fruquintinib for the following investigational uses have not been established and there is no guarantee that it will receive health authority approval or become commercially available in any country for the uses being investigated.

About Fruquintinib for Second-line Treatment of RCC

Single-agent targeted therapy continues to be one of the primary choices for first-line treatment of advanced RCC in China. Notably, advanced RCC patients who have experienced failure with single-agent targeted therapy previously still indicate an unmet medical need.

Results from a proof-of-concept Phase Ib/II study of fruquintinib plus sintilimab were published in *Targeted Oncology* in January 2025. The combination demonstrated promising efficacy and a tolerable safety profile in this setting. At the data cutoff of October 9, 2024, all 20 enrolled previously treated patients were evaluable for efficacy, with a median follow-up duration of 45.7 months. The confirmed ORR was 60.0% and disease control rate (DCR) was 85.0%. Median DoR was 13.9 months and median PFS was 15.9 months. Overall survival ("**OS**") was not reached, and the 36-month OS rate was 58.3%.[v]

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

Hong Kong, China,
June 5, 2025

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, Mr. Gary Zieziula, Dr. Shun Lu and Mr. Shuyun Chen as independent non-executive Directors.

References

i The Global Cancer Observatory, kidney cancer fact sheet. https://gco.iarc.who.int/media/globocan/factsheets/cancers/29-kidney-fact-sheet.pdf. Accessed February 19, 2025.

ii The Global Cancer Observatory, China fact sheet. https://gco.iarc.who.int/media/globocan/factsheets/populations/160-china-fact-sheet.pdf. Accessed February 19, 2025.

iii 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.

iv Sun Q, et al. Discovery of fruquintinib, a potent and highly selective small molecule inhibitor of VEGFR 1, 2, 3 tyrosine kinases for cancer therapy. Cancer Biol Ther. 2014;15(12):1635-45. doi: 10.4161/15384047.2014.964087.

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