信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT
NMPA APPROVAL FOR TYVYT® (SINTILIMAB INJECTION) IN COMBINATION WITH ELUNATE® (FRUQUINTINIB) FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC 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 New Drug Application for the combination of TYVYT® (sintilimab injection) and ELUNATE® (fruquintinib) has been granted approval by the National Medical Products Administration of China ("**NMPA**") for the treatment of patients with locally advanced or metastatic renal cell carcinoma who have failed prior vascular endothelial growth factor receptor-tyrosine kinase inhibitors ("**VEGFR-TKI**") therapy and have not received programmed death receptor-1 ("**PD-1**") or programmed death-ligand 1 ("**PD-L1**") inhibitor therapy in the first-line setting.

The approval 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 patients with locally advanced or metastatic renal cell carcinoma. The study met its primary endpoint of progression free survival ("**PFS**") as assessed by blinded independent central review ("**BICR**").

The approval is a significant milestone for patients with advanced renal cell carcinoma in China. It further validates the potential of the sintilimab plus fruquintinib combination regimen, now approved for two difficult-to-treat cancers. The Company is proud to achieve the 10th approved indication for our PD-1 cornerstone therapy, sintilimab (TYVYT®), and remains committed to advancing clinical value optimization to benefit an even broader population of cancer patients.

About The FRUSICA-2 Trial

Results from the Phase III part of the study were presented at the 2025 European Society for Medical Oncology (ESMO) Congress. As of the PFS final analysis cutoff of February 17, 2025, the median follow-up was 16.6 months. The median PFS as assessed by BICR was 22.2 months with sintilimab plus fruquintinib, compared to 6.9 months with axitinib/everolimus (stratified hazard ratio [HR] 0.373; stratified log-rank p<0.0001). The objective response rate (ORR) was 60.5% vs 24.3% (Odds Ratio 4.622, p<0.0001), and the median duration of response (DoR) was 23.7 months vs 11.3 months, respectively. Overall survival data were still evolving at the time of data cutoff with maturity of approximately 20%. Efficacy benefits were observed in all prognostic risk groups, as defined by the International mRCC Database Consortium (IMDC) criteria. The safety profile of the sintilimab and fruquintinib combination was consistent with the known profiles of each individual treatment. Additional details may be found at clinicaltrials.gov, using identifier NCT05522231.

About Kidney Cancer and Renal Cell Carcinoma

It is estimated that approximately 435,000 new patients were diagnosed with kidney cancer worldwide in 2022.[i] In China, an estimated 74,000 new patients were diagnosed with kidney cancer in 2022.[ii] Approximately 90% of kidney tumors are renal cell carcinoma.

About Sintilimab

Sintilimab, marketed as TYVYT® (sintilimab injection) in China, is a 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.[iii]

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-epidermal growth factor receptor therapy (RAS wild-type) in China. It was included in China's National Reimbursement Drug List in January 2020.

The combination of ELUNATE® (fruquintinib) and TYVYT® (sintilimab injection) has conditional approval in China for the treatment of patients with advanced mismatch repair proficient 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 mainland 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.

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

Hong Kong, China,
May 21, 2026

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, Mr. Shuyun Chen and Dr. Stephen A. Sherwin 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.