信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT
TABOSUN® (IPILIMUMAB N01 INJECTION) RECEIVED APPROVAL BY CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION, IN COMBINATION WITH SINTILIMAB AS NEOADJUVANT TREATMENT FOR COLON 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 TABOSUN® (ipilimumab N01 injection; R&D Code: IBI310), a cytotoxic lymphocyte-associated antigen-4 ("**CTLA-4**") monoclonal antibody ("**mAb**"), has been approved by the National Medical Products Administration of China ("**NMPA**"), in combination with sintilimab as neoadjuvant treatment for stage IIB-III resectable microsatellite instability-high ("**MSI-H**") or mismatch repair deficient ("**dMMR**") colon cancer. TABOSUN® (ipilimumab N01 injection) is the first domestic CTLA-4 mAb approved in China, and also the world's first approved CTLA-4 mAb for neoadjuvant treatment of colon cancer. Short-term neoadjuvant treatment with the ipilimumab N01 and sintilimab combination demonstrated a substantial improvement in pathological complete response, offering the potential to benefit a broader population of patients with MSI-H/dMMR colon cancer.

Resectable MSI-H/dMMR colon cancer urgently requires effective neoadjuvant therapies to improve prognosis

MSI-H/dMMR colon cancer accounts for around 15% of all resectable colon cancer cases[i]. Due to its unique biological characteristics, this class of tumor showed limited sensitivity to chemotherapy and generally responds poorly[ii]. In recent years, immune checkpoint inhibitors have demonstrated significant efficacy in advanced MSI-H/dMMR colon cancer, but a gap remains in the neoadjuvant setting. For locally advanced MSI-H/dMMR colon cancer, the current standard treatment is still direct surgery followed by adjuvant chemotherapy. Under this regimen, approximately 10%-30% of patients experience disease recurrence or metastasis after surgery, while chemotherapy-related toxicities may negatively affect quality of life[iii]. Thus, in the neoadjuvant setting, there remains an urgent need for more effective therapies to improve outcomes for patients with locally advanced MSI-H/dMMR colon cancer.

The world's first dual-IO neoadjuvant therapy: TABOSUN® (ipilimumab injection N01) combined with TYVYT® (sintilimab injection) markedly enhances pathological complete response rate

Immune checkpoint blockade (ICB) therapy targeting PD-1 and CTLA-4 has transformed cancer treatment. The combination of TABOSUN® (ipilimumab injection N01) and TYVYT® (sintilimab injection) as neoadjuvant treatment can significantly improve pathological complete response ("**pCR**") rate and relieve the majority of patients from adjuvant chemotherapy burdens.

Previously, results from a randomized controlled Phase 1b trial evaluating ipilimumab N01 in combination with sintilimab as neoadjuvant treatment for MSI-H/dMMR colon cancer were published in the top-tier journal *Cancer Cell*[iv].

- As of June 17, 2025, 101 patients were enrolled and randomized to receive ipilimumab N01 plus sintilimab (n=52) or sintilimab alone (n=49).

- In the per-protocol (PP) population, the pCR rate in the ipilimumab N01-plus-sintilimab arm was significantly higher than in the sintilimab-alone arm (80.0% vs 47.7%, p=0.0007).

- With median follow-up of 21.4 months, neither group of patients experienced disease recurrence.

The approval is based on results from a randomized, controlled, multicenter, pivotal Phase 3 clinical trial (NeoShot, NCT05890742) which evaluated the safety and efficacy of ipilimumab N01 combined with sintilimab as neoadjuvant therapy and as compared with direct radical surgery for MSI-H/dMMR colon cancer. The primary endpoints are pCR rate and event-free survival (EFS). Interim analysis by the Independent Data Monitoring Committee (iDMC) confirmed that the NeoShot trial has met its primary endpoint.

- As of November 28, 2024, among the first 50 patients of the treatment arm, 41 achieved pathological complete response after neoadjuvant treatment, with a pCR rate of 82%.

- Ipilimumab N01 combined with sintilimab as neoadjuvant treatment did not significantly increase safety risks compared with direct surgery.

Detailed results of NeoShot trial will be presented at future academic conferences or published in academic journals.

About Ipilimumab N01

Ipilimumab N01 (R&D code: IBI310) is a fully human mAb injection independently developed by Innovent. Ipilimumab N01 can specifically bind CTLA-4, thereby blocking CTLA-4 mediated T cell inhibition, promoting T cell activation and proliferation, improving tumor immune response, and achieving anti-tumor effects.[v]

The NDA for ipilimumab N01 in combination with sintilimab as neoadjuvant treatment for stage IIB-III resectable MSI-H/dMMR colon cancer is recently approved by the NMPA.

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-L1 pathway, and reactivates T-cells to kill cancer cells.[vi]

In China, sintilimab has been approved and included in the updated National Reimbursement Drug List ("**NRDL**") for eight 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 NSCLC who progressed after EGFR-tyrosine kinase inhibitor (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;

- For the first-line treatment of unresectable locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma; and

- 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.

Furthermore, the NDA for sintilimab's ninth indication, in combination with ipilimumab N01 as neoadjuvant treatment for stage IIB-III resectable MSI-H/dMMR colon cancer is recently approved conditionally by the NMPA.

The NDA for sintilimab's tenth indication, in combination with fruquintinib for the treatment of locally advanced or metastatic renal cell carcinoma who previously failed systematic treatment, has been accepted by the Center for Drug Evaluation (CDE) of 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 advanced/metastatic 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.

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

Hong Kong, China,
December 29, 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, Mr. Shuyun Chen and Dr. Stephen A. Sherwin as Independent Non-executive Directors.

References:

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