信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT

NEW DRUG APPLICATION OF IBI343 (ARCOTATUG TAVATECAN) ACCEPTED BY NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA FOR ADVANCED REFRACTORY GASTRIC 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 international multi-center phase 3 clinical study (G-HOPE-001, NCT06238843) of arcotatug tavatecan (IBI343, an innovative TOPO1i CLDN18.2 ADC) has completed the per-protocol first interim analysis and reached the primary endpoint. Arcotatug tavatecan demonstrated excellent efficacy and a tolerable safety profile in the treatment of advanced gastric cancer. Based on the positive clinical results, Innovent has submitted the new drug application ("**NDA**") for arcotatug tavatecan to the National Medical Products Administration ("**NMPA**") of China, for the treatment of previously treated locally advanced unresectable or metastatic CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma ("**G/GEJA**") who have received at least two prior systemic therapies. This application has been accepted with priority review. It is the world's first CLDN18.2 ADC to be accepted for regulatory review.

The G-HOPE-001 study is an international, multi-center, randomized, open-label phase 3 clinical trial conducted in China and Japan to evaluate the efficacy and safety of IBI343 monotherapy vs. investigator-selected therapy in subjects with previously treated, Claudin 18.2 positive, locally advanced unresectable or metastatic G/GEJA who have received at least two prior systemic therapies. The primary endpoints of the study are progression-free survival (PFS) and overall survival (OS). The clinical study data are planned to be published in future academic conferences or journals.

Patients with advanced gastric cancer generally have a poor prognosis after initial lines of treatment and are prone to rapid disease progression. There is a lack of effective subsequent treatment options, with median survival of only around half year, highlighting a significant and urgent unmet clinical need. The pivotal Phase 3 clinical study of Arcotatug tavatecan has successfully met its primary endpoint at the first interim analysis. Meanwhile, the NDA for Arcotatug tavatecan has been accepted by the NMPA. Both milestones mark a significant breakthrough in the targeted precision therapy for gastrointestinal tumors. The Company believes that the excellent efficacy and manageable safety profile of this product, if approved, will potentially bring new standardized treatment options and help the adoption of precision diagnosis and treatment for gastrointestinal tumors with targeted therapies, and ultimately deliver longer survival and improved quality of life for patients.

About IBI343 (Arcotatug tavatecan)

IBI343 (Arcotatug tavatecan) is a recombinant human anti-CLDN18.2 monoclonal antibody-drug conjugate (ADC) developed by Innovent Biologics. It specifically binds to the tumor cells expressing CLDN18.2, triggering CLDN18.2-dependent internalization of the ADC. Once inside the cell, the cytotoxic payload is released, resulting in DNA damage and ultimately apoptosis of the tumor cells. The released drug can also diffuse across the plasma membrane to reach and kill neighboring cells, resulting in a "bystander killing effect".

Arcotatug tavatecan is currently under NMPA's review and being explored in solid tumor types such as gastric cancer and pancreatic cancer, including:

- Arcotatug tavatecan is under NMPA's priority review for previously treated locally advanced unresectable or metastatic CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma, based on the positive first interim analysis results from the international multi-center phase 3 clinical study G-HOPE-001;

- Arcotatug tavatecan is under a phase 3 clinical study in China for patients with CLDN18.2-positive advanced pancreatic cancer;

- Arcotatug tavatecan is also being explored in phase 1 clinical studies such as the first-line treatment for patients with gastric cancer and patients with pancreatic cancer.

In October 2025, Innovent Biologics entered into a global strategic partnership with Takeda Pharmaceuticals, which includes granting Takeda exclusive rights for IBI343 (Takeda's R&D code: TAK-921) outside Greater China.

About gastric/gastroesophageal junction adenocarcinoma

Gastric cancer is one of the most common malignant tumors in the world and is one of the leading causes of death due to cancer worldwide. The 5-year survival rate of patients with metastatic gastric cancer is less than 5%[1]. China and Japan are high-incidence areas for gastric cancer[2]. Currently, chemotherapy and immune checkpoint inhibitor therapy combined with fluoropyrimidine and platinum are the standard treatment for patients with advanced metastatic gastric cancer. Systemic therapy has limited efficacy for advanced gastric cancer, especially for third-line and above gastric cancer, the prognosis is usually poor, with few treatment options and short expected survival. The median survival is about half year[3].

CLDN18.2, a tight junction protein specifically expressed in normal gastric mucosa and abnormally highly expressed in gastric cancer and gastroesophageal junction adenocarcinoma (up to pos of casesitive rate: about 80%), is a promising star target for precision treatment of gastric cancer.

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

Hong Kong, China,
June 4, 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

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2. Xu B, Wang JM. Epidemiological study of gastric cancer[J]. Chin J Cancer Prev Treat, 2006,13(1): 81-87.

3. Chan WL, Lam KO, So TH, et al. Third-line systemic treatment in advanced/metastatic gastric cancer: a comprehensive review. Ther Adv Med Oncol. 2019;11:1758835919859990.