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 AND GRANTED PRIORITY REVIEW DESIGNATION TO THE NEW DRUG APPLICATION FOR IBI-351 (KRAS G12C INHIBITOR)

This announcement is made by Innovent Biologics, Inc. (the "**Company**", 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 and granted Priority Review designation to the New Drug Application ("**NDA**") for IBI-351 (KRAS G12C inhibitor) for the treatment of patients with advanced non-small cell lung cancer ("**NSCLC**") harboring KRAS G12C mutation who have received at least one systemic therapy. It is China's first NDA for a KRAS G12C inhibitor and is anticipated to benefit more lung cancer patients harbouring KRAS G12C mutation after approval.

The NDA acceptance and Priority Review designation are based on the results from a single-arm registrational Phase 2 clinical study (NCT05005234) intended to evaluate the efficacy, tolerability and safety of IBI-351 monotherapy in advanced NSCLC patients harbouring KRAS G12C mutation who failed or were intolerant to the standard treatment in China. The results will be presented at the upcoming European Society for Medical Oncology (ESMO) Asia Congress 2023.

Previously, the results of IBI-351 from a Phase 1 clinical trial in patients with solid tumors were updated in an oral presentation at the 2023 American Association for Cancer Research (AACR) Annual Meeting.

- As of February 10, 2023, of the 67 evaluable NSCLC patients, objective response rate ("**ORR**") is 61.2% and disease control rate ("**DCR**") is 92.5%.

- Among 30 patients with NSCLC treated at 600mg BID (the recommended phase 2 dose), better efficacy signal was observed, with ORR 66.7% (confirmed ORR 53.3%) and DCR 96.7%. The median duration of response ("**DoR**") was not reached yet, the 6-month DoR rate was 75.4% (95% CI, 39.8-91.7). The median progression free survival ("**PFS**") was 8.2 months (PFS events 46.7%). The 6-month and 9-month PFS rate were 58.9% (95% CI, 39.0-74.3) and 47.3% (95% CI, 26.1-65.8), respectively, with a median follow-up of 8.1 months, and the data is immature.

- As of November 30, 2022, IBI-351 was well tolerated. No dose limiting toxicity was reported and maximum tolerated dose was not reached. Treatment-related adverse events ("**TRAEs**") occurred in 94.0% (63/67) patients and the most common TRAEs were anemia, pruritus, transferase increased, asthenia, protein urine present and bilirubin increased. The majority of the TRAEs were grade 1-2 with 31.3% of patients reporting ≥grade 3 TRAEs. There were no TRAEs led to treatment discontinuation or death.

Lung cancer is one of the malignancies with the highest incidence and mortality worldwide, among which NSCLC is the most common pathological type, accounting for about 85% of all lung cancers. KRAS mutations are common driver gene mutations in NSCLC, most of which occur in lung adenocarcinoma. KRAS mutations rarely co-exist with driver mutations such as EGFR (epidermal growth factor receptor) and ALK (anaplastic lymphoma kinase), and patients with advanced NSCLC with KRAS G12C mutations are often unable to benefit from the multiple drugs already on the market that target these mutations or rearrangements. After the progress of first-line standard treatment in this population, there are limited second-line treatment options with low effective rate and poor prognosis. The Company is glad about the NDA acceptance of IBI-351 and it could potentially become the first approved KRAS G12C inhibitor in China, which could bring more treatment options to NSCLC patients.

The Company is also exploring the potential of IBI-351 in combination therapy for previously-untreated advanced NSCLC patients with KRAS G12C mutation. Two Phase 1b studies of IBI-351, in combination with cetuximab (ERBITUX®, EGFR inhibitor) and sintilimab (TYVYT®, PD-1 inhibitor) respectively, are currently ongoing.

Besides, IBI-351 monotherapy also demonstrated excellent efficacy and safety in previously-treated advanced colorectal carcinoma ("**CRC**") patients with KRAS G12C mutation, of which the preliminary results were presented at the American Society of Clinical Oncology (ASCO) 2023. In May 2023, IBI-351 became China's first KRAS G12C inhibitor to receive the Center for Drug Evaluation ("**CDE**") of NMPA Breakthrough Therapy Designation ("**BTD**") as monotherapy for CRC patients with KRAS G12C mutation who have received at least two systemic therapies.

About IBI-351 (KRAS G12C Inhibitor)

RAS protein family can be divided into KRAS, HRAS and NRAS categories. KRAS mutations are detected in nearly 90% of pancreatic cancer, 30-40% of colon cancer, and 15-20% lung cancer patients. The occurrence of KRAS G12C mutation subset is more frequently observed than those with ALK, ROS1, RET and TRK 1/2/3 mutations combined.

IBI-351 is a novel, orally active, potent KRAS G12C inhibitor designed to effectively target the GTP/GDP exchange, an essential step in pathway activation, by modifying the cysteine residue of KRAS G12C protein covalently and irreversibly. Preclinical cysteine selectivity studies demonstrated high selectivity of IBI-351 towards G12C. Subsequently, IBI-351 effectively inhibits the downstream signal pathway to induce tumor cells' apoptosis and cell cycle arrest.

In September 2021, the Company and GenFleet Therapeutics entered into an exclusive license agreement for the development and commercialization of IBI-351 (GenFleet R&D code: GFH925) in China (including mainland China, Hong Kong, Macau and Taiwan) with additional option-in rights for global development and commercialization.

In January 2023, the CDE of NMPA granted BTD for IBI-351 for the treatment of patients with advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy. In May 2023, the CDE of NMPA granted another BTD for IBI-351 for the treatment of advanced CRC patients with KRAS G12C mutation who have received at least two systemic therapies. In November 2023, the CDE of NMPA accepted and granted Priority Review designation to the NDA for IBI-351 for the treatment of advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy.

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

Hong Kong, China,
November 24, 2023

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 LelandCooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen and Mr. Gary Zieziula as Independent Non-executive Directors.