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 TALETRECTINIB (ROS1 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 the New Drug Application ("**NDA**") for taletrectinib, a next-generation ROS oncogene 1 ("**ROS1**") tyrosine kinase inhibitor ("**TKI**"), for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer ("**NSCLC**") who have been previously treated with ROS1 TKIs.

The NDA acceptance is based on positive results from the Phase 2 TRUST-I trial (NCT04395677), a multicenter, open-label, single-arm trial that evaluated taletrectinib in Chinese ROS1-positive NSCLC patients. Results of an interim analysis from the TRUST-I trial were presented at the European Lung Cancer Congress (ELCC) 2023.

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 with more than one million people globally diagnosed with NSCLC annually. It is estimated that approximately 3% of people with NSCLC in China are ROS1-positive. There are approved first-generation TKIs for people with newly diagnosed advanced or metastatic ROS1-positive NSCLC and no approved therapies for people whose ROS1-positive NSCLC has progressed following treatment with these medicines. Up to 35% of people newly diagnosed with metastatic ROS1-positive NSCLC have tumors that have spread to their brain (brain metastases), and the number increases to approximately 55% for those whose cancer has progressed following initial treatment.

Taletrectinib demonstrated best-in-class efficacy and safety profile in the TRUST-I trial. The Company is pleased of the NDA acceptance of taletrectinib and will work closely with the regulatory authorities, together with our partner AnHeart Therapeutics ("**AnHeart**"), to bring this precision therapy to NSCLC patients who are in need of novel treatment options, especially those with acquired resistant mutations or with brain metastases.

About Taletrectinib

Taletrectinib is an oral, potent, brain penetrant, selective, next-generation potential best-in-class ROS1 inhibitor being evaluated for the treatment of ROS1-positive NSCLC.

Taletrectinib was evaluated in ROS1-positive NSCLC patients in two Phase 2 trials, TRUST-I (NCT04395677) in China, and TRUST-II (NCT04919811), a global pivotal trial. Positive interim results from TRUST-II trial were reported at the ELCC 2023, and positive interim results from TRUST-II trial were reported at the European Society of Medical Oncology Congress 2023.

Taletrectinib was granted Breakthrough Therapy Designation("**BTD**") by the Centre for Drug Evaluation (CDE) of NMPA in 2022 for the treatment of adult patients with advanced or metastatic ROS1-positive NSCLC who have previously been treated with a ROS1 TKI as well as those who have not previously been treated by a ROS1 TKI (TKI-naive). In addition, taletrectinib has also been granted BTD for the treatment of ROS1-positive NSCLC by the U.S. Food and Drug Administration in the United States.

In June 2021, the Company and AnHeart entered into an exclusive license agreement for the co-development and commercialization of taletrectinib in Greater China, including mainland China, Hong Kong, Macau and Taiwan.

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

Hong Kong, China,
November 22, 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 Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen and Mr. Gary Zieziula as Independent Non-executive Directors.