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 SECOND 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 Center for Drug Evaluation ("**CDE**") of China's National Medical Products Administration ("**NMPA**") has accepted a second New Drug Application ("**NDA**") for taletrectinib adipate capsule ("**taletrectinib**"), a next-generation ROS oncogene 1 ("**ROS1**") tyrosine kinase inhibitor ("**TKI**"), as a first-line treatment for adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer ("**NSCLC**") who have not previously been treated with ROS1 TKIs.

In November 2023, the NMPA accepted taletrectinib's first NDA and granted Priority Review Designation for treating adult patients with locally advanced or metastatic ROS1-positive NSCLC who have been previously treated with ROS1 TKIs. Both the above two NDAs are based on positive results from the Phase 2 TRUST-I (NCT04395677) trial. Data from an interim analysis of TRUST-I was presented at the European Lung Cancer Congress ("**ELCC**") 2023 and additional data from TRUST-I is planned to be presented at an upcoming medical meeting in 2024.

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 the people with NSCLC in China are ROS1-positive. There are two approved first-generation TKIs for people with newly diagnosed advanced or metastatic ROS1-positive NSCLC. However, no approved therapies are available for patients whose ROS1-positive NSCLC has progressed after the treatment with these medicines. Additionally, up to 35% of patients 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 second NDA acceptance of taletrectinib and will continue communications with our partner AnHeart Therapeutics ("**AnHeart**") and regulatory authorities in China, hoping to bring this new generation of targeted therapy to all appropriate patients with ROS1-positive NSCLC as a standard initial treatment option.

About Taletrectinib

Taletrectinib is an oral, potent, brain penetrant, selective and next-generation potential best-in-class ROS1 inhibitor.

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-I 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.

In 2022, taletrectinib was granted Breakthrough Therapy Designation by the CDE of China's NMPA for the treatment of adult patients with advanced or metastatic ROS1-positive NSCLC who are ROS1 TKI naive as well as those who have previously been treated with ROS1 TKIs.

Taletrectinib has also been granted Breakthrough Therapy Designation in the United States for the treatment of ROS1-positive NSCLC by the U.S. Food and Drug Administration (FDA).

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,
March 5, 2024

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, Mr. Gary Zieziula and Dr. Shun Lu as Independent Non-executive Directors.