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 APPROVES SECOND NEW DRUG APPLICATION OF ROS1 INHIBITOR DOVBLERON® (TALETRECTINIB ADIPATE CAPSULE)

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 National Medical Products Administration of China ("**NMPA**") has approved the second New Drug Application ("**NDA**") of DOVBLERON® (taletrectinib adipate capsule), a next-generation ROS proto-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**").

In December 2024, DOVBLERON® (taletrectinib adipate capsule) was approved by the NMPA for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who have been previously treated with ROS1 TKIs. DOVBLERON® (taletrectinib adipate capsule) is the 13th addition to the Company's commercial portfolio, representing an innovative precision therapy expected to benefit more lung cancer patients alongside the Company's TKI franchise.

The approval is based on positive results from the pivotal Phase 2 TRUST-I trial (NCT04395677), a multicenter, open-label, single-arm trial that evaluated the safety, tolerability and efficiency of taletrectinib in Chinese patients with advanced ROS1-positive NSCLC. The findings, which was presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and published in the Journal of Clinical Oncology (JCO), demonstrated that taletrectinib continued to show high and durable overall responses and robust activity against intracranial lesions. In ROS1 TKI-naïve (n=106) patients, confirmed objective response rate ("**cORR**", as assessed by an independent review committee ("**IRC**")) and intracranial cORR reached as high as 91% and 88%, respectively. After median follow-up of 23.5 months in TKI-naïve patients, median duration of response (IRC-assessed) and median progression-free survival (IRC-assessed) were not reached.

About ROS1-positive Non-small Cell Lung Cancer

Lung cancer continues to have one of the highest global incidences and mortality rates, with NSCLC accounting for about 85% of all cases. In China, it is estimated that approximately 2.6% of patients living with NSCLC are ROS1-positive[1]. Despite recent progress for patients with ROS1-positive NSCLC, there remains a need for more effective and tolerable treatment options. In patients with metastatic ROS1-positive NSCLC that progressed following initial treatment, many have tumors spread to their brain (up to 55%) or acquired resistance mutations, including G2032R. Next-generation ROS1 TKIs demonstrated robust intracranial and G2032R activity. In the clinical management of ROS1-positive NSCLC patients, the first-line application of the new generation ROS1 TKIs can bring a prolonged progression-free survival and provide patients with greater survival benefits.

About DOVBLERON® (Taletrectinib Adipate Capsule)

DOVBLERON® (taletrectinib adipate capsule) is an oral, potent, central nervous system-active, selective, next-generation ROS1 inhibitor. Taletrectinib, the active ingredient in DOVBLERON® is being evaluated for the treatment of patients with advanced ROS1-positive NSCLC in two Phase 2 single-arm pivotal studies: TRUST-I (NCT04395677) in China, and TRUST-II(NCT04919811), a global study.

DOVBLERON® (taletrectinib adipate capsule) was approved by the NMPA for the treatment of: 1) adult patients with locally advanced or metastatic ROS1-positive NSCLC who have previously been treated with ROS1 TKIs; and 2) adult patients with locally advanced or metastatic ROS1-positive NSCLC.

Taletrectinib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration ("**FDA**") for the treatment of patients with ROS1-positive NSCLC and other NSCLC indications, and Breakthrough Therapy Designations by both the FDA and NMPA for the treatment of patients with locally advanced or metastatic ROS1-positive NSCLC. Based on pooled results of the TRUST-I and TRUST-II clinical studies, Nuvation Bio Inc. (NYSE: NUVB) submitted an NDA for taletrectinib to the FDA for the treatment of patients with advanced ROS1-positive NSCLC (line agnostic, full approval). This NDA was accepted by the FDA for priority review in December 2024.

In June 2021, Innovent and AnHeart Therapeutics (Hangzhou) Co. Ltd., a Nuvation Bio Inc. company, 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,
January 3, 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 and Mr. Shuyun Chen as Independent Non-executive Directors.

Reference

1. Zhang et al. Prevalence of ROS1 fusion in Chinese patients with non-small cell lung cancer. Thorac Cancer. 2019 Jan;10(1):47-53.