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 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 National Medical Products Administration of China ("**NMPA**") has approved the 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**") who have been previously treated with ROS1 TKIs. DOVBLERON® marks 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 taletrectinib in Chinese patients with advanced ROS1-positive NSCLC. The findings, presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and published in the Journal of Clinical Oncology (JCO), demonstrated the potential of DOVBLERON® to address unmet needs, particularly in patients with limited therapeutic options after treatment with prior ROS1-targeted therapies.

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]. Furthermore, brain metastases are a common challenge, affecting up to 35% of patients newly diagnosed with metastatic ROS1-positive NSCLC, and increasing to as much as 55% of patients whose cancer has progressed following initial treatment. In addition, patients treated with approved ROS1 TKIs often develop resistance mutations to these therapies, representing a major limitation for patients in terms of duration of response. The approval of DOVBLERON® provides a new and effective treatment option for patients who are no longer responding to previously approved therapies.

About DOVBLERON® (Taletrectinib Adipate Capsule)

DOVBLERON® is an oral, potent, central nervous system-active, selective, next-generation ROS1 inhibitor specifically designed for the treatment of patients with advanced ROS1-positive NSCLC. 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.

In December 2024, DOVBLERON® was approved by China's NMPA for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who have previously been treated with ROS1 TKIs. In addition, a second NDA for taletrectinib was accepted and granted Priority Review Designation by China's NMPA for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who have not previously been treated with ROS1 TKIs.

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 U.S. FDA and China's 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 U.S. FDA for the treatment of patients with advanced ROS1-positive NSCLC (line agnostic, full approval).

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,
December 20, 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 and Ms. Qian Zhang as Executive Directors and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen, 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.