信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT
THE THIRD-GENERATION EGFR TKI LIMERTINIB RECEIVED APPROVAL BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR THE TREATMENT OF LUNG CANCER

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 new drug application ("**NDA**") of limertinib, the third-generation epidermal growth factor receptor ("**EGFR**") tyrosine kinase inhibitor ("**TKI**"), received approval by the National Medical Products Administration of China ("**NMPA**") for the treatment of adult patients with locally advanced or metastatic EGFR T790M-mutated non-small cell lung cancer ("**NSCLC**").

In a Phase 2b pivotal study evaluating 301 patients with locally advanced or metastatic EGFR T790M-mutated NSCLC, limertinib demonstrated robust efficacy and safety. The independent review committee ("**IRC**") assessed an overall response rate ("**ORR**") of 68.8% and a disease control rate (DCR) of 92.4%. The median progression-free survival ("**PFS**") was 11.0 months, the median duration of response (DoR) was 11.1 months. Among patients with evaluable intracranial lesions, the central nervous system (CNS) best ORR assessed by the IRC was 65.9% with a median PFS of 10.6 months. The safety profile was consistent with other EGFR-targeting agents of the same class.

In addition, a Phase 3 clinical trial comparing limertinib to gefitinib in the first-line treatment of locally advanced or metastatic NSCLC harboring EGFR mutations met its primary endpoint. A separate NDA for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions (19DEL) or exon 21 L858R mutations was accepted in August 2024 and is currently under NMPA review.

Limertinib is the 14th product in the Company's commercial portfolio and represents a cutting-edge addition to its strong TKI franchise, offering an innovative precision therapy expected to benefit more EGFR-mutated advanced NSCLC patients. We remain steadfast in our commitment to reinforcing the leadership position in oncology and driving forward treatment solutions through innovation and cooperation.

About EGFR mutation NSCLC

Lung cancer continues to have one of the highest global incidences and mortality rates[i], with NSCLC accounting for about 85% of all cases. Around 70% of NSCLC patients are diagnosed with locally advanced or metastatic disease that cannot be surgically resection. EGFR is the most common driver mutation in NSCLC, affecting 30% to 50% of Asian NSCLC patients. EGFR-TKIs are the recommended first-line standard of care for this group, with the third-generation EGFR inhibitors offering the broadest applicability.

About Limertinib

Limertinib is an orally-administrated, third-generation EGFR TKI with proprietary rights, approved by the NMPA for the treatment of adult patients with locally advanced or metastatic EGFR T790M-mutated NSCLC. A second NDA of limertinib is currently under review by the NMPA for first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions (19DEL) or exon 21 L858R mutations.

In a multi-center, randomized, double-blind, controlled Phase 3 clinical trial, the efficacy and safety of limertinib were compared to gefitinib in the first-line treatment of patients with locally advanced or metastatic NSCLC harboring EGFR mutations. The trial met its primary endpoint, and the results will be presented at future academic conferences or published in academic journals.

In October 2024, the Company and ASK Pharm entered into a strategic collaboration and license agreement regarding limertinib in Mainland China.

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

Hong Kong, China
January 17, 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

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[i] Bray F, et al. Global cancer statistics 2022. CA Cancer J Clin. 2024 May-Jun;74(3):229-263. doi: 10.3322/caac.21834. Epub 2024 Apr 4. PMID: 38572751.