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 FROM THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR THE FIRST-LINE 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 of limertinib, the third-generation epidermal growth factor receptor ("**EGFR**") tyrosine kinase inhibitor ("**TKI**"), received approval from the National Medical Products Administration of China ("**NMPA**") for the first-line treatment in adult patients with locally advanced or metastatic non-small cell lung cancer ("**NSCLC**") harboring EGFR exon 19 deletions or exon 21 L858R mutations.

The approval of this new indication is supported by positive results from a randomized, double-blind, positive-controlled Phase 3 clinical trial. A total of 337 treatment-naïve patients with EGFR-sensitive mutation-positive locally advanced or metastatic NSCLC were enrolled and randomized at the ratio of 1:1 to receive either limertinib or gefitinib. The primary endpoint was independent review committee (IRC)-assessed progression-free survival ("**PFS**").

The data showed that limertinib significantly prolonged median PFS compared to gefitinib (20.7 months vs. 9.7 months), representing a 56% risk reduction in disease progression or death (hazard ratio ("**HR**") 0.44; 95% CI: 0.34-0.58; $p < 0.0001$). In patients with central nervous system ("**CNS**") lesions at baseline, median CNS PFS was also significantly longer with limertinib (20.7 months vs. 7.1 months), corresponding to a 72% risk reduction for CNS progression or death (HR 0.28; 95% CI: 0.10-0.82; $p = 0.0136$), underscoring its robust intracranial activity and clinical utility in such population with high-unmet-needs.

The safety profile of limertinib was consistent with that of known EGFR-targeted therapies. Adverse events were predominantly mild to moderate and well-tolerated, with no new safety signals identified during the clinical trial. Full data and analysis from the pivotal Phase 3 study will be published in academic journals.

As a next-generation EGFR TKI, limertinib is poised to significantly improve survival outcomes for mutation-positive patients. We have built a rich portfolio of precision therapies for lung cancer, including limertinib, Retsevmo® (selpercatinib), Dupert® (fulzerasib) and DOVBLERON® (taletrectinib), with ongoing efforts to enhance their synergistic value. The Company remains steadfast in its commitment to reinforcing its leadership position in oncology and driving forward treatment solutions through innovation and cooperation.

About EGFR mutation-positive NSCLC

Lung cancer continues to have one of the highest global incidences and mortality rates, 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 mutations are particularly prevalent among Asian NSCLC patients, affecting 30% to 50% of Asian NSCLC patients. EGFR-TKIs are the recommended first-line standard of care for this group, with third-generation EGFR -TKIs offering the broadest applicability.

About Limertinib

Limertinib is an orally-administrated, third-generation EGFR TKI with proprietary rights, approved by the NMPA for: 1) the treatment of adult patients with locally advanced or metastatic EGFR T790M-mutated NSCLC, who have previously experienced disease progression during or after treatment with EGFR TKI; and 2) first-line treatment of adult patients with locally advanced or metastatic NSCLC carrying EGFR exon 19 deletions or exon 21 L858R mutations.

In October 2024, the Company and Jiangsu Aosaikang Pharmaceutical Co. Ltd. entered into a commercial collaboration agreement regarding limertinib in China.

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

Hong Kong, China,
April 25, 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

[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.