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Innovent

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 APPROVED CHINA'S FIRST KRAS G12C INHIBITOR DUPERT®

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 Centre for Drug Evaluation of the National Medical Products Administration of China (“**NMPA**”) has approved Dupert® (fulzerasib) for the treatment of adult patients with advanced non-small cell lung cancer (“**NSCLC**”) harboring Kristen rat sarcoma viral oncogene homolog G12C (“**KRAS G12C**”) mutation who have received at least one systemic therapy. As China’s first approved KRAS G12C inhibitor, Dupert® (fulzerasib) is anticipated to benefit more lung cancer patients with the KRAS G12C mutation.

The New Drug Application approval is based on the results from a single-arm registrational Phase 2 clinical study (NCT05005234) intended to evaluate the efficacy, tolerability and safety of fulzerasib monotherapy in advanced NSCLC patients with KRAS G12C mutation who failed or were intolerant to the standard treatment in China. As of the data cut-off date (December 13, 2023), a total of 116 NSCLC subjects were enrolled and evaluable. Fulzerasib was generally well-tolerated and demonstrated encouraging antitumor activity. The confirmed objective response rate (ORR) assessed by the independent radiology review committee (IRRC) was 49.1% (95% CI: 39.7-58.6). Disease control rate (DCR) was 90.5% (95% CI: 83.7, 95.2). The median duration of response (DoR) was not reached. Median progression-free survival (PFS) was 9.7 months (95% CI: 5.6-11.0), and median overall survival (OS) was not yet reached.

Lung cancer has one of the highest incidence and mortality rates worldwide, with NSCLC being the most common type. KRAS mutations are common driver gene mutations in NSCLC. Patients with advanced NSCLC and KRAS G12C mutations often cannot benefit from the currently available drugs. Dupert[®] (fulzerasib) has become the first KRAS G12C inhibitor approved in China, and will soon benefit more patients with advanced NSCLC harboring KRAS G12C mutations, driving the progress of precision treatment for lung cancer.

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

Hong Kong, China,
August 21, 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.