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 OLVEREMBATINIB FOR THE TREATMENT OF CML-CP PATIENTS WHO ARE RESISTANT AND/OR INTOLERANT TO 1st AND 2nd GENERATION TKI TREATMENT

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 olverembatinib has been officially approved by the National Medical Products Administration ("**NMPA**") of China for the treatment of adult patients with chronic-phase chronic myeloid leukemia ("**CML-CP**") who are resistant and/or intolerant to 1st and 2nd generation tyrosine kinase inhibitors ("**TKIs**"). This approval represents another important milestone of olverembatinib after the drug was first approved in 2021 and successfully included into the 2022 National Reimbursement Drug List, which will further benefit a broader population of patients with chronic myeloid leukemia ("**CML**") in China.

This approval is based on the results of an open-label, national multicenter, randomized-controlled pivotal registrational Phase 2 clinical study (HQP1351CC203). The study was designed to evaluate the efficacy and safety of olverembatinib in patients with CML-CP who were resistant and/or intolerant to 1st and 2nd generation TKIs. Patients were randomly assigned to the olverembatinib treatment group and the Best Available Treatment ("**BAT**") control group. Clinical data showed that patients receiving olverembatinib showed a statistically significant improvement compared to patients receiving BAT in the control group, meeting the primary endpoint of event-free survival (EFS).

CML is a hematological malignancy associated with white blood cells. The introduction of BCR-ABL TKIs has significantly improved the management of CML. However, 20% to 40% of patients still fail to achieve desired treatment outcome due to drug resistance or intolerance to TKI[1-3], eventually leading to disease progression or even death. Today, TKI resistance has become a global challenge for the treatment of CML, and there is an urgent clinical need for safe and effective new generation of drugs.

As the first and only marketed third generation BCR-ABL inhibitor in China, olverembatinib has outstanding effects on BCR-ABL and a variety of BCR-ABL mutants (including T315I mutation), and has a good safety profile and significant efficacy in patients resistant to 1st and 2nd generation TKIs. In November 2021, olverembatinib was approved in China for the treatment of adult patients with TKI-resistant CML-CP or accelerated-phase CML (CML-AP) harboring the T315I mutation. In January 2023, olverembatinib has been officially included into the China National Reimbursement Drug List, further enhancing the affordability and accessibility of the drug. The commercialization of the drug in China is jointly undertaken by the Company and Ascentage Pharma (a company listed on The Stock Exchange of Hong Kong Limited, stock code: 6855).

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

Hong Kong, China,
November 17, 2023

*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 as Executive Director, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen and Mr. Gary Zieziula as Independent Non-executive Directors.*

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1 O'Brien SG, Guilhot F, Larson R, et al. Imatinib compared with interferon and low-dose cytarabine for newly diagnosed chronic-phase chronic myeloid leukemia. Engl J Med . 2003 Mar 13;348(11):994-1004.

2 Jabbour E, Kantarjian H. Chronic myeloid leukemia: 2014 update on diagnosis, monitoring, and management. Am J Hematol. 2014 May;89(5):547-56.

3 Larson R, Hochhaus A, Hughes T, et al. Nilotinib vs imatinib in patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase: ENESTnd 3-year follow-up. Leukemia. 2012 Oct;26(10):2197-203.