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 ACCEPTED AND GRANTED PRIORITY REVIEW DESIGNATION TO A NEW DRUG APPLICATION FOR OLVEREMBATINIB FOR THE TREATMENT OF DRUG-RESISTANT CHRONIC MYELOID LEUKEMIA

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 Center for Drug Evaluation ("**CDE**") of the China National Medical Products Administration ("**NMPA**") has accepted and granted Priority Review designation (in a CDE's public notice ended on July 18, 2022) to a new drug application ("**NDA**") that will support the full approval of olverembatinib in patients with chronic-phase chronic myeloid leukemia ("**CML-CP**") who are resistant and/or intolerant of first and second generation tyrosine kinase inhibitors ("**TKIs**"). Following the conditional NDA approval in November 2021, the acceptance for the latest application marks another milestone and will potentially bring olverembatinib to benefit a broader population of patients with chronic myeloid leukemia ("**CML**"). The Company and Ascentage Pharma Group International (stock code: 6855) ("**Ascentage Pharma**") are mutually committed to the commercialization of olverembatinib in the China market.

In November 2021, the NMPA granted a conditional approval to olverembatinib for the treatment of adult patients with TKI-resistant CML-CP or accelerated-phase CML ("**CML-AP**") harboring the T315I mutation as confirmed by a validated diagnostic test, thus filling an urgent treatment gap that has long hindered the clinical outcome in Chinese patients with TKI-resistant CML harboring the T315I mutation.

The acceptance and Priority Review designation for this application are based on the results from an open-label, randomized, controlled, confirmatory Phase II pivotal study (study code: HQP1351CC203) which previously served as the basis for a Breakthrough Therapy designation to olverembatinib by the CDE in March 2021. The study is designed to evaluate the efficacy and safety of olverembatinib in patients with CML-CP who are resistant and/or intolerant to first and second generation TKIs, with the event-free survival ("**EFS**") as its primary endpoint. A total of 144 patients were enrolled and randomized to either receive olverembatinib or the control group to receive the current best available treatment (BAT). Results show that olverembatinib significantly improved the EFS compared to the control group and has met the pre-specified superiority criteria. Detailed results from this study will be released at an upcoming academic conference.

CML is a hematologic malignancy of the white blood cells. The introduction of BCR-ABL TKIs has significantly improved the clinical practice of CML. However, acquired resistance to TKIs remains a major challenge in the treatment of CML. BCR-ABL tyrosine kinase mutations represent a key mechanism of acquired drug resistance and there is an urgent unmet medical need for a safe and effective treatment option. As the first and only third generation BCR-ABL inhibitor approved for the treatment of drug-resistant CML in China, olverembatinib is able to effectively target a spectrum of BCR-ABL mutants, including T315I. The Company looks forward to the full approval of the product in the near future, hoping to benefit a broader population of patients with TKI-resistant CML in China with this novel treatment option as soon as possible.

About Olverembatinib

Developed by Ascentage Pharma with support from the National Major New Drug Discovery and Manufacturing Program in China, the orally active, third generation BCR-ABL inhibitor olverembatinib is the first China-approved third generation BCR-ABL inhibitor targeting drug-resistant CML. Olverembatinib can effectively target a spectrum of BCR-ABL mutants, including the T315I mutation.

In November 2021, olverembatinib was approved by the NMPA for the treatment of adult patients with TKI-resistant CML-CP or CML-AP harboring the T315I mutation as confirmed by a validated diagnostic test. In March 2021, it was granted the Breakthrough Therapy designation by the CDE for the treatment of patients with CML-CP who are resistant and/or intolerant of first and second generation TKIs.

In overseas, olverembatinib was cleared by the US Food and Drug Administration ("**FDA**") in July 2019 to directly enter a Phase Ib study. Since 2018, the clinical results of olverembatinib have been selected for oral presentations at the American Society of Hematology ("**ASH**") Annual Meetings for four consecutive years, and was nominated for "Best of ASH" in 2019. To date, olverembatinib has been granted one Fast Track designation and three Orphan Drug designations from the FDA for the treatment of CML, acute lymphoblastic leukemia, and acute myeloid leukemia; and one Orphan Designation from the European Medicines Agency of the European Union for the treatment of CML.

In July 2021, the Company and Ascentage Pharma reached the agreement regarding the joint development and commercialization of olverembatinib in China.

* *Olverembatinib has not been approved for any indication in the U.S.*

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

Hong Kong, China,
July 19, 2022

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.