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 THE NEW DRUG APPLICATION FOR PARSACLISIB (PI3Kδ INHIBITOR)

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 National Medical Products Administration ("**NMPA**") of China has accepted and granted Priority Review designation to the New Drug Application ("**NDA**") for parsaclisib (PI3Kδ inhibitor, R&D code: IBI376) for the treatment of adult patients with relapsed or refractory follicular lymphoma ("**FL**") who had received at least two previous systemic therapies.

The acceptance and Priority Review designation for this NDA are based on the results from a multi-center, single-arm, open-label pivotal Phase II study conducted in China (NCT04298879), most recently presented at the 2022 American Society of Clinical Oncology (ASCO) meeting. As of December 12, 2021, the data cut-off date, the objective response rate ("**ORR**") seen with parsaclisib monotherapy was 86.9% (53/61, 95% CI: 75.8%, 94.2%) in FL patients who had received at least two previous systemic treatments (n=61), 19 patients (31.1%) had a complete response ("**CR**") and 34 patients (55.7%) achieved a partial response ("**PR**"). The median duration of response ("**DOR**") and median progression-free survival ("**PFS**") were not yet achieved, and the majority of patients continued to be in remission. Among the 61 patients treated with parsaclisib, 27 patients (44.3%) experienced grade ≥ 3 TEAEs, the most common grade ≥ 3 TEAEs was a decrease in neutrophil count (n=10, 16.4%). The results also showed that parsaclisib was generally well tolerated with a manageable safety profile.

FL is the second most prevalent type of non-Hodgkin's lymphoma ("**NHL**"), accounting for about one-fifth of NHL patients, and is the most common indolent NHL. Although most patients with FL respond to first-line therapy, relapse is common and is difficult to cure with existing therapies, placing a significant burden of disease on patients. The NDA for parsaclisib in China was accepted and granted Priority Review designation, which is a milestone for the clinical research for parsaclisib, and is also expected to add to the innovative product pipeline for the Company in the field of hematology. The Company will cooperate with the local regulatory authorities and looks forward to receiving the approval and launch-to-market of the product in the near future, hoping to bring more treatment options for patients with relapsed or refractory follicular lymphoma.

About Parsaclisib

Parsaclisib (IBI376) is a highly selective, next-generation investigational novel oral inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ) discovered by Incyte (NASDAQ: INCY). Incyte is currently developing pivotal trials of parsaclisib in combination with ruxolitinib for the treatment of patients with myelofibrosis.

In December 2018, the Company and Incyte entered into a strategic collaboration for three clinical-stage product candidates, including parsaclisib (PI3Kδ inhibitor). Under the terms of the collaboration agreement, the Company has received the rights to develop and commercialize parsaclisib in Mainland China, Hong Kong, Macau and Taiwan.

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

Hong Kong, China,
January 6, 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.