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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 UPDATE ON THE NEW DRUG APPLICATION FOR PARSACLISIB (PI3K δ 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.

In January 2023, the National Medical Products Administration of China had accepted a New Drug Application (“**NDA**”) of the Company for parsaclisib (PI3K δ inhibitor, R&D code: IBI-376) for the treatment of adult patients with relapsed or refractory follicular lymphoma (“**FL**”) who have received at least two prior systemic therapies.

As an update to this application, due to the partner’s adjustment of the product’s overseas development strategy after the application submission, the Company’s additional investment in completing the Phase 3 confirmatory trial for the product will increase substantially and require a significantly longer study period. Considering its overall research and development (“**R&D**”) strategy and product value management, the Company has decided to voluntarily withdraw the current NDA for parsaclisib and will focus its resources on more important pipeline assets, and continue to adhere to high-quality product development to meet more unmet medical needs.

The Company believes that the withdrawal of the current application will have very limited impact on the future product sales of the Company based on relatively small patient population and the crowded market competition for the indication, but will have a more positive effect on the Company’s overall R&D investment return. The Company has established a robust product portfolio, with ten commercialized products to date contributing sustainable sales growth, and a more diversified innovation pipeline that provides a solid foundation for the Company's long-term sustainable growth.

About Parsaclisib

Parsaclisib (R&D code: IBI-376) is a highly selective, next-generation oral inhibitor of phosphatidylinositol 3-kinase delta (PI3K δ). In December 2018, the Company entered into a collaboration with Incyte (NASDAQ: INCY), whereby the Company was granted the rights to develop and commercialise parsaclisib in China.

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

Hong Kong, China,
September 28, 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.