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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)**

## **INSIDE INFORMATION**

### **FDA ISSUES COMPLETE RESPONSE LETTER FOR SINTILIMAB IN COMBINATION WITH PEMETREXED AND PLATINUM CHEMOTHERAPY FOR THE FIRST-LINE TREATMENT OF PEOPLE WITH NONSQUAMOUS NON-SMALL CELL LUNG CANCER**

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 U.S. Food and Drug Administration (“**FDA**”) has issued a complete response letter (“**CRL**”) for the Biologics License Application (“**BLA**”) for the investigational medicine sintilimab injection, a PD-1 inhibitor in combination with pemetrexed and platinum chemotherapy for the first-line treatment of people with nonsquamous non-small cell lung cancer (“**NSCLC**”). Sintilimab is being developed by the Company and Eli Lilly and company (“**Lilly**”).

The letter indicates that the review cycle is complete but the FDA is unable to approve the application in its current form, consistent with the outcome of the Oncologic Drugs Advisory Committee Meeting in February. The CRL includes a recommendation for an additional clinical study, specifically a multiregional clinical trial comparing standard of care therapy for first line metastatic NSCLC to sintilimab with chemotherapy utilizing a non-inferiority design with an overall survival endpoint.

The Company and Lilly are assessing next steps for the sintilimab program in the U.S.

The Company remains confident in the value of sintilimab. The Company has gained tremendous experience and know-how, and established a strong registration team throughout the registrational process, allowing the Company to be more confident and committed to bringing our innovative drugs to global markets through a defined pathway. The Company will continue pursuing our strategy of transforming into a global biopharma company and bringing high-quality innovative medicines to patients around the world.

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

Hong Kong, China, March 24, 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, Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu and Dr. Kaixian Chen as Independent Non-executive Directors.*