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 THE NEW DRUG APPLICATION FOR EQUECABTAGENE AUTOLEUCEL FOR THE TREATMENT OF RELAPSED AND/OR REFRACTORY MULTIPLE MYELOMA

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 the New Drug Application ("**NDA**") for Equecabtagene Autoleucel (Innovent R&D code: IBI326，IASO Biotherapeutics ("**IASO Bio**") R&D code: CT103A), a fully human anti-B cell maturation antigen ("**BCMA**") chimeric antigen receptor ("**CAR**") T-cell therapy for the treatment of relapsed and/or refractory multiple myeloma ("**R/R MM**").

The acceptance of NDA is based on data from a single-arm, open-label, multi-center phase 1/2 study (NCT05066646) being conducted in China. Study results showed that Equecabtagene Autoleucel has excellent safety and efficacy profiles, low immunogenicity given a fully-human single-chain variable fragment ("**scFv**"), robust expansion and prolonged persistence in vivo. It will potentially offer a breakthrough treatment option for patients with R/R MM. The data from the phase 1/2 clinical study of Equecabtagene Autoleucel was presented in an oral presentation at the 63rd American Society of Hematology (ASH) Annual Meeting (Abstract #547) and the updated data was accepted as an oral presentation at the 27th Annual Congress of the European Hematology Association (EHA) Virtual Meeting (Abstract #S187), to be held on June 9-12, 2022.

Multiple myeloma ("**MM**") is a deadly blood cancer that often infiltrates the bone marrow causing anemia, kidney failure, immune problems, and bone fractures. For multiple myeloma patients, common first-line drug treatments include proteasome inhibitors, immunomodulatory drugs, and alkylating agents. While treatment may result in remission, most patients will inevitably enter the relapsed or refractory stage as there's currently no cure to the disease. As a result, there is a significant unmet need for patients with R/R/MM.

According to Frost & Sullivan, the number of new MM cases in China rose from 18,900 in 2016 to 21,100 in 2020 and is expected to increase to 24,500 by 2025. The total number of patients diagnosed with MM in China increased from 69,800 in 2016 to 113,800 in 2020 and is expected to rise to 182,200 by 2025. The Company will work with regulatory authorities on the NDA review and hope to benefit more MM patients with this breakthrough therapy.

About Equecabtagene Autoleucel

Equecabtagene Autoleucel is an innovative therapy co-developed by Innovent Biologics and IASO Bio. Previous studies indicate subjects with R/R MM who received high-dose BCMA-targeting CAR T-cells may achieve better remission but have worse adverse events. Moreover, once the disease progresses again, the re-infusion of CAR T-cells will not be effective. To solve this dilemma, Equecabtagene Autoleucel has been developed, a lentiviral vector containing a CAR structure with a fully human scFv, CD8a hinger and transmembrane, 4-1BB co-stimulatory and CD3ζ activation domains. Based on strict selection and screening, utilizing a proprietary in-house optimization platform and integrated in house manufacture process improvement, the construct of the BCMA CAR-T is potent and Equecabtagene Autoleucel shows prolonged persistency in patients.

Equecabtagene Autoleucel is the first CAR-T therapy in China that is self-developed with proprietary whole-process product development and the first BCMA-targeting CAR T-cell therapy in China with its NDA formally accepted by the NMPA. It is an innovative therapy co-developed by IASO Bio and Innovent. In February 2021, Equecabtagene Autoleucel was granted "Breakthrough Therapy Designation" by the NMPA. In February 2022, Equecabtagene Autoleucel was granted "Orphan Drug Designation" by the Food and Drug Administration for the treatment of R/R MM.

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

Hong Kong, China,
June 2, 2022

As at the date of this announcement and following the appointment of Mr. Gary Zieziula as Director, 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.