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 APPROVES THE BCMA CAR-T THERAPY FUCASO® (EQUECABTAGENE AUTOLEUCEL) FOR THE TREATMENT OF RELAPSED 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 approved the New Drug Application ("**NDA**") for FUCASO® (Equecabtagene Autoleucel, co-developed and co-commercialized by the Company and IASO Bio, Innovent R&D code: IBI326, IASO Bio R&D code: CT103A), the first fully-human BCMA-directed chimeric antigen receptor ("**CAR**") T cell therapy for adult patients with relapsed or refractory multiple myeloma ("**RRMM**") who have received at least three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

FUCASO® (Equecabtagene Autoleucel) is a BCMA-directed CAR T cell therapy, using lentivirus as a gene vector to transfect autologous T cells. The CAR contains a fully-human scFv, CD8a hinge and transmembrane, and 4-1BB-mediated co-stimulation and CD3ζ activation domains. Based on rigorous selection and screening of the molecular structures, and comprehensive in vivo and in vitro evaluation, FUCASO® has demonstrated rapid and potent efficacy as well as prolonged persistency in RRMM patients, providing higher and deeper responses and long-term clinical benefit.

The NDA approval was based on the results from the FUMANBA-1 clinical study (CTR20192510, NCT05066646), a multi-center Phase I/II registrational clinical trial conducted in China to evaluate the efficacy of Equecabtagene Autoleucel in patients with RRMM. In June 2023, updated data from this ongoing study was presented as a poster presentation (Abstract Number: 8025) at the 2023 Annual Meeting of the American Society of Clinical Oncology (ASCO), in which Equecabtagene Autoleucel demonstrated remarkable efficacy and favorable safety profiles.

A total of 103 subjects received a dose of 1.0×10^6 CAR-T cells/kg, with a median follow-up time of 13.8 (0.4, 27.2) months.

- Among the 101 evaluable patients, the overall response rate ("**ORR**") was 96%, and the stringent complete response/complete response ("**sCR/CR**") rate was 74.3%. Median time to response ("**mTTR**") was only 16 days, and the 12-month PFS rate was 78.8%. 95% of the patients achieved minimal residual disease ("**MRD**") negativity, and all sCR/CR patients achieved MRD negativity. Of the 12 patients with prior CAR-T therapy, 9 achieved CR, and 5 achieved sCR (including 4 patients that sustained sCR for over 18 months post-infusion). In 89 patients without prior CAR-T therapy, 78.7% reached sCR/CR.

- Of the 103 patients, only one experienced grade ≥3 cytokine release syndrome ("**CRS**"), and 2 experienced grade 1-2 immune effector cell-associated neurotoxicity syndrome ("**ICANS**"). All patients with CRS or ICANS recovered after the treatment.

- Equecabtagene Autoleucel was still detectable in 50% and 40% respectively of the patients who completed 12-month and 24-month follow-ups after infusion. Only 19.4% of the patients were anti-drug antibody ("**ADA**")-positive after Equecabtagene Autoleucel infusion.

Multiple Myeloma ("**MM**") is one of the most common blood cancers characterized by abnormal proliferation of clonal plasma cells. For MM 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 a result, there is a significant unmet need for patients with relapsed or refractory multiple myeloma. According to Frost & Sullivan, new MM cases per year in China rose from 20,100 in 2018 to 22,400 in 2022 and are expected to increase to 25,700 by 2027.

FUCASO®, as an innovative fully-human BCMA-directed T cell therapy, demonstrates robust and long-lasting efficacy and outstanding safety in long-term follow-up data from the registrational clinical study, which underscores its potential to be a pioneering treatment option for patients with RRMM. The Company is pleased about the approval of FUCASO® and believes that it could benefit RRMM patients as the first approved BCMA CAR-T therapy in China.

About FUCASO® (Equecabtagene Autoleucel)

FUCASO® (Equecabtagene Autoleucel) is an innovative fully-human anti-BCMA CAR-T cell therapy which uses lentivirus as a gene vector to transfect autologous T cells. The CAR contains a fully-human scFv, CD8a hinge and transmembrane, and 4-1BB-mediated co-stimulation and CD3ζ activation domains. Based on rigorous selection and screening of the molecular structures, and comprehensive in vivo and in vitro evaluation, FUCASO® has demonstrated rapid and potent efficacy as well as prolonged persistency in RRMM patients.

FUCASO® (Equecabtagene Autoleucel) is approved by China's NMPA for the treatment of RRMM. The Company and IASO Bio are responsible for joint development and commercialization of FUCASO® (Equecabtagene Autoleucel) for the treatment of RRMM in mainland China.

Furthermore, Equecabtagene Autoleucel received Orphan Drug Designation ("**ODD**") designation from the U.S. Food and Drug Administration ("**FDA**") for the treatment of RRMM and obtained the U.S. FDA IND approval. Equecabtagene Autoleucel also received Regenerative Medicine Advanced Therapy ("**RMAT**") and Fast Track ("**FT**") Designations in February 2023 from the FDA. In addition to multiple myeloma, the NMPA has accepted another IND application for the new extended indication of Neuromyelitis Optica Spectrum Disorder (NMOSD).

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

Hong Kong, China,
July 03, 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.