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 TAFOLECIMAB INJECTION (ANTI-PCSK-9 ANTIBODY)

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 tafolecimab injection (anti-PCSK-9 antibody, R&D code: IBI306) for the treatment of primary hypercholesterolemia (including heterozygous familial hypercholesterolemia and non-familial hypercholesterolemia) and mixed dyslipidemia.

The acceptance of NDA is based on based on the study results of three phase 3 registration clinical trials (CREDIT-1, CREDIT-2 and CREDIT-4): compared with placebo, tafolecimab injection reduced low-density lipoprotein cholesterol (LDL-C) levels by about 57% ~ 65%, and maintained long-term therapeutic efficacy. In addition, tafolecimab injection also significantly reduced total cholesterol (TC), non-high-density lipoprotein cholesterol (Non-HDL-C), apolipoprotein B (ApoB), and lipoprotein a (Lp (a)) levels. With a high percentage of patients achieving lipid reduction goals, a long administration interval (once every 6 weeks), and overall favorable safety profiles, tafolecimab injection is expected to be a potent treatment for patients with primary hypercholesterolemia (including heterozygous familial hypercholesterolemia and non-familial hypercholesterolemia) and mixed dyslipidemia.

In recent years, the blood lipid level of the Chinese population has gradually increased, and the prevalence of dyslipidemia has increased significantly with an overall prevalence of 40.4% in Chinese adults. The increase of serum cholesterol level in the population will lead to an increase of about 9.2 million cardiovascular disease events in China between 2010 ~ 2030. Dyslipidemia, characterized by elevated LDL-C or Total Cholesterol (TC), is an important independent risk factor for atherosclerotic cardiovascular disease.

According to the 2020 China Cardiovascular Health and Disease Report, the diagnostic, treatment and control rate of dyslipidemia in Chinese adults remain low. The percentage of patients with dyslipidemia who met the LDL-C reduction goal is even more alarming. Current lipid-lowering therapies do not meet the clinical needs in patients with hyperlipidemia. Anti-PCSK-9 monoclonal antibody has a mechanism of action different from existing lipid-lowering drugs and can effectively reduce LDL-C levels, which is expected to provide a better treatment option for Chinese patients with hypercholesterolemia. Although there are imported products in the Chinese market, there is still room for improvement in terms of affordability, accessibility and convenience. The Company will cooperate with the regulatory authorities and we are looking forward to the approval and launch-to-market of the product in the near future, hoping to benefit the large number of patients with hypercholesterolemia in China with this high-quality medicine as soon as possible.

About Tafolecimab Injection (anti-PCSK-9 antibody)

Tafolecimab injection, developed by Innovent, is an lgG2 fully human monoclonal antibody that can specifically bind to PCSK-9 and reduce LDL-C level by inhibiting PCSK-9-mediated low-density lipoprotein receptor (LDLR) endocytosis, subsequently enhancing the clearance of LDL-C, resulting in a reduction in LDL-C level.

As of now, three registration trials of tafolecimab injection have met the primary endpoint. The results from phase I/II clinical study have been published in JACC Asia, an internationally renowned journal of cardiology. CREDIT-2 phase III study results have been presented at the ACC meeting 2022.

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

Hong Kong, China,
June 13, 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, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen and Mr. Gary Zieziula as Independent Non-executive Directors.