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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

THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION APPROVES ANTI-PCSK9 MONOCLONAL ANTIBODY SINTBILO® (TAFOLECIMAB INJECTION) FOR THE TREATMENT OF ADULT PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIA

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 SINTBILO® (tafolecimab injection, anti-protein convertase subtilisin/kexin type 9 enzyme (“**PCSK9**”) monoclonal antibody) for the treatment of adult patients with primary hypercholesterolemia (including heterozygous familial and non-familial hypercholesterolemia) and mixed dyslipidemia. As the first domestic PCSK9 inhibitor approved in China, SINTBILO® (tafolecimab injection) is the Company’s first drug entering the cardiovascular field, as well as the Company’s tenth product in its commercial portfolio.

SINTBILO® (tafolecimab injection), independently developed by the Company, is an IgG2 fully human monoclonal antibody that can specifically bind to PCSK9 and reduce low-density lipoprotein cholesterol (“**LDL-C**”) level by inhibiting PCSK9-mediated low-density lipoprotein receptor (“**LDLR**”) endocytosis, subsequently enhancing the clearance of LDL-C, resulting in a reduction in LDL-C level.

The NDA approval was based on the results of three Phase 3 registrational clinical trials (CREDIT-1, CREDIT-2, and CREDIT-4). The approved dosing regimens of SINTBILO® (tafolecimab injection) include 150mg Q2W, 450mg Q4W, and 600mg Q6W, all of which are effective in reducing LDL-C, total cholesterol (“**TC**”), non-high-density lipoprotein cholesterol (“**non-HDL-C**”), apolipoprotein B (“**ApoB**”), and lipoprotein a (“**Lp(a)**”) levels as observed in the Phase 3 registrational clinical trials. The diverse treatment regimens will provide more individualized choices for cardiologists and patients.

The prevalence of cardiovascular diseases is continuously increasing in China, among which atherosclerotic cardiovascular disease (“ASCVD”) is the leading cause contributing more than 40% of deaths in Chinese residents. Dyslipidemia is one of the most common and dangerous risk factors of ASCVD. In particular, elevated LDL-C is the major risk factor driving the occurrence and progression of ASCVD. The current clinical management of multiple lipid-lowering agents can hardly reach guideline-recommended LDL-C targets in Chinese patients.

SINTBILO[®] (tafolecimab injection), as the first domestic fully human anti-PCSK9 monoclonal antibody approved in China, has demonstrated strong lipid-lowering efficacy and favorable safety in multiple Phase 3 registrational clinical trials. The clinical development of tafolecimab condensed the efforts of many domestic experts, demonstrated the recognition from the regulatory authorities, and the strength and capabilities of the Company in the field of cardiovascular diseases. Moreover, SINTBILO[®] (tafolecimab injection) has the advantage of a longer dosing interval compared with other marketed PCSK9 monoclonal antibody agents and a significant decrease in Lp(a). The Company is pleased that the approval of SINTBILO[®] (tafolecimab injection), marks a meaningful milestone for the Company’s strategic position in the cardiovascular and metabolism (CVM) area, and believe it will bring a new treatment option for cholesterol management in China.

About SINTBILO[®] (Tafolecimab Injection)

SINTBILO[®] (tafolecimab injection), independently developed by the Company, is an IgG2 fully human monoclonal antibody that can specifically bind to PCSK9 and reduce LDL-C level by inhibiting PCSK9-mediated LDLR endocytosis, subsequently enhancing the clearance of LDL-C, resulting in a reduction in LDL-C level.

SINTBILO[®] (tafolecimab injection) is indicated as adjunct to diet, in combination with statins or statins and other lipid-lowering therapies, for the treatment of adult patients with primary hypercholesterolemia (including heterozygous familial and non-familial hypercholesterolemia) and mixed dyslipidemia who have failed to achieve LDL-C goals by using moderate or higher doses of statins, to reduce LDL-C, TC and ApoB levels.

About CREDIT Registrational Clinical Studies

CREDIT-1 is a randomized, double-blind, placebo-controlled phase 3 clinical study to assess the efficacy and safety of tafolecimab in Chinese subjects with non-familial hypercholesterolemia (hypercholesterolemia with cardiovascular risk) (ClinicalTrials.gov, NCT04289285). At week 48, compared with placebo, the treatment difference of mean change in LDL-C level from baseline was -65.04% (97.5% CI: -70.22%, -59.86%) for tafolecimab 450mg Q4W group and -57.31% (97.5% CI: -63.95%, -50.68%) for tafolecimab 600mg Q6W group (P < 0.0001 for both comparisons). The proportion of patients with a 50% or greater reduction in LDL-C from baseline was 87.8% and 71.8%, respectively, compared with 1.0% and 2.0% in placebo group, respectively, both P < 0.0001 in comparison with placebo.

CREDIT-2 is a randomized, double-blind, placebo-controlled phase 3 study evaluating the efficacy and safety of tafolecimab in Chinese patients with heterozygous familial hypercholesterolemia (ClinicalTrials.gov, NCT04179669). At week 12, compared with placebo, the treatment difference of mean change in LDL-C level from baseline was -57.37% (97.5% CI, -69.21%, -45.54%) for tafolecimab 150mg Q2W group and -61.90% (97.5% CI: -73.40%, -50.41%) for tafolecimab 450mg Q4W group (P < 0.0001 for both comparisons). The proportion of patients with a 50% or greater reduction in LDL-C from baseline was 59.6% and 75.0%, respectively, compared with both 0 in placebo group, both P < 0.0001 in comparison with placebo.

CREDIT-4 is a randomized, double-blind, placebo-controlled phase 3 clinical study to assess the efficacy and safety of IBI306 in Chinese patients with hypercholesterolemia (including non-familial hypercholesterolemia and heterozygous familial hypercholesterolemia) (ClinicalTrials.gov, NCT04709536). At week 12, compared with placebo, the treatment difference of mean change in LDL-C level from baseline was -63.02% (97.5% CI, -66.48%, -59.56%) for tafolecimab 450mg Q4W group (P < 0.0001 for comparison). The proportion of patients with a 50% or greater reduction in LDL-C from baseline was 90.5% in tafolecimab 450mg Q4W group and 2.0% in placebo group (P < 0.0001 for comparison).

Clinically meaningful and statistically significant reductions from baseline in TC, non-HDL-C, ApoB, and Lp(a) level were observed in all 3 clinical studies.

In a pooled safety analysis of 1091 patients with primary hypercholesterolemia who received tafolecimab, adverse events during the double-blind treatment phase of tafolecimab included upper respiratory tract infection (9.6%), urinary tract infection (7.3%), injection site reaction (5.7%), arthralgia (3.1%), back pain (2.2%), and nasopharyngitis (2.0%).

The efficacy and safety of tafolecimab have also received recognition from the academic community. The main results of the CREDIT-1 study were presented in a poster at the American Heart Association (AHA) Scientific Sessions 2022ⁱ, and the study will be published in a peer-reviewed academic journal soon. The main results of the CREDIT-2 study were presented in a conference poster at the American College of Cardiology (ACC) Scientific Sessions 2022ⁱⁱ, and the study was published in BMC Medicineⁱⁱⁱ. The CREDIT-4 study was published online in JACC: Asia in July 2023^{iv}.

References

- i Huo Y, Li Y, Zhang P, et al. Efficacy and Safety of Tafolecimab in Chinese Patients With Non-Familial Hypercholesterolemia (CREDIT-1) : A 48-Week Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial. *Circulation*. 2022;146 (Suppl_1) :10111.
- ii Zhou Y, Chai M, He Y, et al. Efficacy and Safety of Tafolecimab in Chinese Patients with Heterozygous Familial Hypercholesterolemia (CREDIT-2) : A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial. *ACC*. 2022; 1188-005/5.
- iii Chai M, He Y, Zhao W, et al. Efficacy and safety of tafolecimab in Chinese patients with heterozygous familial hypercholesterolemia: a randomized, double-blind, placebo-controlled phase 3 trial (CREDIT-2). *BMC Med*. 2023; 21 (1) :77. Published 2023 Feb 28.
- iv Qi L, Liu D, Qu Y, et al. Tafolecimab in Chinese Patients With Hypercholesterolemia (CREDIT-4). *JACC: Asia*. 2023

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

Hong Kong, China,
August 16, 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.