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 OF MAZDUTIDE FOR TYPE 2 DIABETES

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 Centre for Drug Evaluation ("**CDE**") of the National Medical Products Administration of China ("**NMPA**") has accepted the second New Drug Application ("**NDA**") of mazdutide (R&D code: IBI362), a glucagon-like peptide-1 receptor ("**GLP-1R**") and glucagon receptor ("**GCGR**") dual agonist for the treatment of adults with type 2 diabetes ("**T2D**").

The NDA is mainly based on the results of two Phase 3 clinical studies, which respectively evaluate the efficacy and safety of mazdutide as monotherapy (DREAMS-1, NCT05628311) and in combination with oral antidiabetic drugs (OADs) (DREAMS-2, NCT05606913) in Chinese patients with T2D. These studies demonstrate that mazdutide is superior to placebo and dulaglutide 1.5 mg in glycemic control, weight reduction, and improvements on multiple cardiovascular and renal indicators. In both studies, the safety profile of mazdutide is similar to previous clinical studies and those of other GLP-1R agonists, with no new safety concerns. Detailed study data will be published at academic conferences or in peer-reviewed journals.

Mazdutide is the first GLP-1R/GCGR dual agonist to achieve success in Phase 3 trials for T2D. Once approved, it is expected to provide a novel treatment option for the vast population of diabetic patients in China, with comprehensive benefits in glycemic control, weight reduction and multiple metabolic benefits. The Company will work closely with the regulatory authorities hoping to provide a better treatment option for Chinese patients with T2D.

About Type 2 Diabetes (T2D)

According to the International Diabetes Federation's 2021 global overview of diabetes, China has the highest number of diabetes patients worldwide, with an estimation of over 140 million in 2021 and over 174 million by 2045[1]. Poor glycemic control can lead to irreversible microvascular and macrovascular complications, such as decreased visual acuity, blindness, renal dysfunction, peripheral neuropathy, myocardial infarction, stroke and amputation[2]. The high prevalence of diabetes, along with its serious complications, poses a significant threat to human health. At present, there are many therapeutic regimens for diabetes. In addition to effectively controlling blood glucose, the development of new hypoglycemic drugs has begun to include the additional benefits of weight loss, cardiovascular risk reduction and kidney protection for patients with diabetes[3].

About Mazdutide (IBI362)

The Company entered into an exclusive license agreement with Eli Lilly and Company (Lilly) for the development and potential commercialization of OXM3 (also known as mazdutide), a GLP-1R and GCGR dual agonist, in China. As a mammalian oxyntomodulin (OXM) analogue, mazdutide promotes insulin secretion, lowers blood glucose and reduces body weight similar to GLP-1 receptor agonists. Additionally, it may increase energy expenditure and improve hepatic fat metabolism by activating the glucagon receptor. Mazdutide has strong efficacy in weight loss and lowering glucose levels in clinical studies. It also offers multiple cardio-metabolic benefits, such as reducing waist circumference, blood lipids, blood pressure, blood uric acid, liver enzymes, and liver fat content, while improving insulin sensitivity.

Mazdutide has two NDAs accepted by China's NMPA for review, including:

- For the chronic weight management in adults with obesity or overweight; and
- For the glycemic control in adults with T2D.

Currently, a total of five Phase 3 clinical studies of mazdutide are in progress, including:

- Phase 3 clinical study conducted in Chinese adults with overweight or obesity (GLORY-1);
- Phase 3 clinical study conducted in Chinese adults with moderate to severe obesity (GLORY-2);
- Phase 3 clinical study in newly treated Chinese patients with T2D (DREAMS-1);
- Phase 3 clinical study comparing mazdutide and dulaglutide in Chinese patients with T2D (DREAMS-2); and
- Phase 3 clinical study comparing mazdutide and semaglutide in Chinese patients with T2D and obesity (DREAMS-3).

Among them, GLORY-1, DREAMS-1 and DREAMS-2 have reached the study endpoints.

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

Hong Kong, China,
August 1, 2024

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 and Ms. Qian Zhang as Executive Directors and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen, Mr. Gary Zieziula, Dr. Shun Lu and Mr. Shuyun Chen as Independent Non-executive Directors.

References

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2. Gregg EW, Sattar N, Ali MK. The changing face of diabetes complications. Lancet Diabetes Endocrinol. Published online 2016. doi: 10.1016/S2213-8587 (16) 30010-9

3. Nauck MA, Quast DR, Wefers J, Meier JJ. GLP-1 receptor agonists in the treatment of type 2 diabetes-state-of-the-art. Mol Metab. Published online 2020. doi: 10.1016/j.molmet.2020. 101102