信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT MAZDUTIDE RECEIVED APPROVAL FROM CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES

This announcement is made by Innovent Biologics, Inc. (the "**Company**" or "**Innovent**", 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 new drug application ("**NDA**") of mazdutide, a first-in-class dual glucagon ("**GCG**")/glucagon-like peptide-1 ("**GLP-1**") receptor agonist, received approval for its second indication by the National Medical Products Administration of China ("**NMPA**") for glycemic control in adults with type 2 diabetes ("**T2D**"). Mazdutide is the world's first dual GCG/GLP-1 receptor agonist approved for glycemic control in adults with T2D. It is expected to support disease management for the vast T2D population in China, achieving comprehensive benefits in glycemic control, weight reduction and hepato-cardio-renal metabolic indicators.

China has the highest number of T2D affected patients, facing urgent challenges in long-term glucose management and complication prevention

China leads the world in diabetes prevalence, with 140 million adults affected (1 in 4 global cases). Diabetes is a chronic condition where prolonged hyperglycemia can lead to severe complications, such as cardiovascular diseases, nephropathy, retinopathy and neuropathy. These complications not only endanger patients' lives and health but also impose a significant economic burden on families and society.

In recent years, the treatment paradigm for diabetes has progressively shifted from glycemic control alone to a comprehensive, patient-centric management strategy. This approach integrates glycemic control, weight management, cardiovascular risk factor mitigation, and prevention/treatment of hepato-cardio-renal complications.

The American Diabetes Association ("**ADA**")/European Association for the Study of Diabetes ("**EASD**") Consensus Report on the Management of Hyperglycemia in T2D has formally recognized weight reduction as a core therapeutic target. Weight loss should be prioritized not only to improve glycemic outcomes but also to reduce the risk of weight-related complications. For some patients with T2D, achieving a 5% - 15% reduction in body weight is recommended as a primary treatment goal.

Mazdutide: superior glycemic control and weight loss, with hepato-cardio-renal metabolic benefits, supporting Healthy China 2030

Building upon the established effects of GLP-1 receptor agonists, dual GCG/GLP-1 receptor agonists simultaneously improve the two core pathogenic mechanisms of diabetes – insufficient insulin secretion and insulin resistance, thus, delivering comprehensive benefits beyond glycemic control, including weight loss, and hepato-cardio-renal metabolic improvements. As a safe, effective and convenient novel therapeutic option, mazdutide addresses the critical needs of long-term glucose management and complication prevention in T2D, actively supporting the realization of the "Healthy China 2030" vision.

The approval was based on two Phase 3 clinical trials (DREAMS-1 [NCT05628311] and DREAMS-2 [NCT05606913]), which evaluated the efficacy and safety of mazdutide as monotherapy and in combination with oral antidiabetic drugs, respectively, in Chinese participants with T2D. **These studies demonstrated mazdutide's superiority over placebo or dulaglutide 1.5 mg in glycemic control and weight reduction, while also showing improvements in multiple cardiometabolic, hepatic and renal parameters.**

- DREAMS-1: for the efficacy estimand, at Week 24, the mean changes in HbA1c from baseline in the mazdutide 4 mg group, mazdutide 6 mg group and placebo group were -1.57%, -2.15%, and -0.14%, respectively; the proportion of participants with HbA1c <7% were 68.6%, 87.4% and 10.7%, respectively; the mean percent change in body weight from baseline were -5.61%, -7.81% and -1.26%, respectively; and the proportion of participants with HbA1c <7% and a body weight reduction≥5% were 40.6%, 64.9%, and 0%, respectively.

- DREAMS-2: for the efficacy estimand, at Week 28, the mean changes in HbA1c from baseline in the mazdutide 4 mg group, mazdutide 6 mg group and dulaglutide 1.5 mg group were -1.69%, -1.73% and -1.38%, respectively; the proportion of participants with HbA1c <7% were 71.2%, 74.2% and 62.1%, respectively; the mean percent change in body weight from baseline were -7.31%, -9.24% and -2.86%, respectively; and the proportion of participants with HbA1c <7% and a body weight reduction≥5% were 50.1%, 64.3%, and 19.4%, respectively.

Mazdutide exhibited a safety profile consistent with previous clinical studies and other GLP-1R agonists, with no new safety signals identified. DREAMS-1 results were orally presented (Abstract #: 306-OR) at the 85th Scientific Sessions of the ADA; and DREAMS-2 results were presented as a late-breaking oral presentation (Abstract #: LBA 16) at the 60th Annual Meeting of the EASD. Based on the innovative mechanism and robust evidence of mazdutide, it has been recommended in expert consensus in China.

It is worth noting that the mazdutide injection device demonstrates significant improvements in both convenience and safety compared to existing injection devices of the same type. The device features a hidden needle, ensuring the needle remains out of sight throughout the process, effectively reducing patient anxiety associated with injections. Additionally, it is a single-use device, designed for immediate disposal after use, which significantly lowers the risk of drug contamination caused by reuse or improper handling. Furthermore, the injection device incorporates innovative X-cross-section technology, delivering a smoother and painless injection experience, thereby enhancing patient comfort and treatment adherence.

Mazdutide has shown multiple metabolic benefits for cardiovascular, hepatic and renal systems while maintaining an excellent safety profile. The successful approval of mazdutide reflects the national drug regulatory authority's strong endorsement of its clinical value and safety profile, while fully validating our innovative R&D capabilities in metabolic therapeutics. We hope mazdutide will provide superior treatment options for Chinese patients with T2D and help alleviate the disease burden on our society. We will continue focusing on advancing innovative therapies in oncology, autoimmune, cardiovascular and metabolic, and ophthalmology disease areas to fulfill our commitment of serving more patients worldwide.

About Diabetes

According to the 2021 global diabetes overview by the International Diabetes Federation, China leads the world in the number of patients with diabetes, with an estimated 140 million cases in 2021 and projected to reach 174 million by 2045[1]. Poor glycemic control can lead to irreversible microvascular and macrovascular complications, including reduced visual acuity, blindness, renal dysfunction, peripheral neuropathy, myocardial infarction, stroke and amputation[2]. The high prevalence of diabetes and its serious complications pose a significant threat to human health. Currently, various therapeutic approaches are available for diabetes management. In addition to controlling blood glucose, new hypoglycemic drugs are being developed to offer additional benefits such as weight loss, cardiovascular risk reduction and kidney protection[3].

About Mazdutide

Innovent entered into an exclusive license agreement with Eli Lilly and Company (Lilly) for the development and potential commercialization of mazdutide, a dual GCG/GLP-1 receptor agonist, in China. As a mammalian oxyntomodulin (OXM) analogue, in addition to the effects of GLP-1 receptor agonists on promoting insulin secretion, lowering blood glucose and reducing body weight, mazdutide may also increase energy expenditure and improve hepatic fat metabolism through the activation of glucagon receptor. Mazdutide has demonstrated excellent weight loss and glucose-lowering effects in clinical studies, as well as reducing waist circumference, blood lipids, blood pressure, serum uric acid, liver enzymes, liver fat content and improved insulin sensitivity.

Mazdutide has conducted seven Phase 3 clinical studies, including:

- GLORY-1: A Phase 3 clinical study conducted in Chinese adults with overweight or obesity;
- GLORY-2: A Phase 3 clinical study conducted in Chinese adults with moderately to severely obesity;
- GLORY-3: A Phase 3 clinical study comparing mazdutide versus semaglutide in Chinese adults with overweight of obesity accompanied metabolic-associated fatty liver disease (MAFLD);
- GLORY-OSA: A Phase 3 trial in Chinese participants with obstructive sleep apnea (OSA) and obesity;
- DREAMS-1: A Phase 3 clinical study conducted in Chinese adults with untreated T2D;

- DREAMS-2: A Phase 3 clinical study comparing mazdutide versus dulaglutide in Chinese adults with T2D who have poor glycemia control with oral medication; and

- DREAMS-3: A Phase 3 clinical study comparing mazdutide versus semaglutide in Chinese adults with T2D and obesity.

Among these, GLORY-1, DREAMS-1, and DREAMS-2 have already met their primary endpoints and the other four studies are currently ongoing.

In addition, several new clinical studies of mazdutide are initiated or planned, including:

- A Phase 3 trial in adolescents with obesity; and

- New studies in patients with metabolic dysfunction-associated steatohepatitis (MASH) and heart failure with preserved ejection fraction (HFpEF).

* Mazdutide has received NMPA approval for two indications:

First Indication: as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial Body Mass Index ("**BMI**") of:

- BMI $\geq$ 28 kg/m² (obesity); or

- BMI $\geq$ 24 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hyperglycemia, hypertension, dyslipidemia, fatty liver, or obstructive sleep apnea syndrome etc.);

Second Indication (Newly Approved): glycemic control in adults with T2D:

Monotherapy

- For adults with T2D who have inadequate glycemic control despite diet and exercise interventions.

Combination Therapy

- For adults with T2D who still have poor glycemic control despite diet and exercise, plus Metformin and/or sulfonylureas, or Metformin and/or SGLT2 inhibitors (SGLT2i).

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

Hong Kong, China
September 19, 2025

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, Mr. Gary Zieziula, Dr. Shun Lu, Mr. Shuyun Chen and Dr. Stephen A. Sherwin as independent non-executive Directors.

References

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