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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 ACCEPTED THE FIRST NEW DRUG APPLICATION FOR MAZDUTIDE FOR CHRONIC WEIGHT MANAGEMENT

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 (“**NMPA**”) of China has accepted the first New Drug Application (“**NDA**”) for mazdutide (R&D code: IBI-362), a glucagon-like peptide-1 receptor (“**GLP-1R**”) and glucagon receptor (“**GCGR**”) dual agonist, for chronic weight management in adults with obesity or overweight.

In January 2024, the Phase 3 GLORY-1 (NCT05607680) clinical trial of mazdutide in Chinese adults with overweight or obesity met the primary endpoints and all key secondary endpoints. Mazdutide 4 mg and 6 mg showed superiority over placebo in terms of body weight reduction and multiple weight-related and cardiometabolic endpoints. The safety profile was similar to that observed in previous clinical studies of mazdutide, with no new safety signals observed. The Company plans to release detailed results from the GLORY-1 study in medical conferences or journals later in 2024.

As a chronic disease with complex underlying causes, obesity is one of the leading risk factors for type 2 diabetes, fatty liver, cardiovascular and cerebrovascular diseases, kidney diseases, joint diseases, sleep apnea and cancers. With economic development and lifestyle changes, the number of people with overweight and obesity in China has jumped to the highest in the worldⁱ. With early prevention and timely intervention of overweight and obesity, the risks for numerous chronic diseases such as cardiovascular and cerebrovascular diseases, type 2 diabetes, hypertension, and fatty liver could be effectively reduced, which would improve quality of life and alleviate disease burdens. However, weight loss and management through lifestyle intervention alone is usually difficult to achieve or maintain for many people living with obesity or overweight. Safe and efficacious weight management pharmacotherapies could significantly reduce body weight and improve weight-related cardiometabolic risk factors and health-related outcomes.

Mazdutide is the first GLP-1R/GCGR dual agonist to successfully complete Phase 3 trials in support of a NDA submission. As a new generation of weight-loss drugs activating both GLP-1 and GCGR, mazdutide could bring an efficacious, safe and easy-to-use treatment option to the vast and ever-growing population with overweight or obesity in China. The Company will work closely with the regulatory authorities, hoping to provide a safe and effective weight management medication for Chinese people with overweight or obesity.

About Mazdutide (IBI-362)

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, with the effects of GLP-1R agonists to promote insulin secretion, lowering blood glucose and reducing body weight, mazdutide may also increase energy expenditure and improve hepatic fat metabolism through the activation of GCGR. Mazdutide has demonstrated robust weight loss and glucose-lowering effects in clinical studies as well as improvements in multiple cardio-metabolic indicators including reducing waist circumference, blood lipids, blood pressure, blood uric acid, liver enzymes, liver fat content and improved insulin sensitivity. Currently, five Phase 3 clinical studies of mazdutide in Chinese adults with overweight or obesity (GLORY-1 and GLORY-2) and type 2 diabetic (DREAMS-1, DREAMS-2 and DREAMS-3) subjects are underway, where GLORY-1 study has met the primary and all key secondary endpoints.

In February 2024, the first NDA of mazdutide was accepted by the CDE of the NMPA of China for chronic weight management in adults with obesity or overweight.

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

Hong Kong, China,
February 07, 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 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.

ⁱ Pan XF, Wang L, Pan A. *Epidemiology and determinants of obesity in China. Lancet Diabetes Endocrinol* 2021; 9: 373-92.