信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT
THE FIRST PHASE 3 CLINICAL TRIAL OF MAZDUTIDE IN CHINESE ADULTS WITH OVERWEIGHT OR OBESITY MET THE PRIMARY AND ALL KEY SECONDARY ENDPOINTS

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 first Phase 3 clinical trial of mazdutide (R&D code: IBI-362), a glucagon-like peptide-1 receptor ("**GLP-1R**") and glucagon receptor ("**GCGR**") dual agonist, in Chinese adults with overweight or obesity ("**GLORY-1**") met the primary endpoints and all key secondary endpoints. The Company plans to submit the first new drug application ("**NDA**") of mazdutide for weight management to the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China (NMPA) in the near term.

GLORY-1 (NCT05607680) is a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the efficacy and safety of mazdutide in Chinese adults with overweight or obesity. A total of 610 participants were randomized to receive mazdutide 4 mg, 6 mg or placebo in the 48-week double-blind treatment period.

The GLORY-1 study met both primary endpoints – mazdutide 4 mg and 6 mg showed superiority to placebo in terms of the percentage change in body weight from baseline to week 32 and the proportion of participants with a weight loss of ≥5% at week 32. The weight-loss efficacy was further improved from week 32 to week 48.

Furthermore, all key secondary endpoints were met, including the proportion of participants with a weight loss of ≥10% or ≥ 15%, as well as the changes in waist circumference, systolic blood pressure, triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), total cholesterol, serum uric acid, and alanine aminotransferase (ALT). Mazdutide demonstrates superiority to placebo in all the above weight-loss and cardiometabolic endpoints.

During the double-blind treatment period, the safety profile of mazdutide was similar to those observed in previous clinical studies, and no new safety signals were observed.

With economic development and lifestyle changes, the number of obese population in China has jumped to the highest in the world . As a chronic disease with a complex etiology, obesity is one of the leading risk factors of type 2 diabetes, fatty liver, cardiovascular and cerebrovascular diseases, kidney diseases, joint diseases, sleep apnea in addition to cancers. Lifestyle intervention is a basic treatment option for patients with overweight or obesity. However, a considerable percentage of patients fail to achieve the desired weight loss goal through merely lifestyle intervention, highlighting the unmet clinical need for more effective and safe therapies for the Chinese obese population.

As a novel GLP-1R/GCGR dual agonist, mazdutide has accumulated clinical data on more than a thousand Chinese participants. The results of the GLORY-1 study further confirm that mazdutide has robust weight loss effect with favorable safety and tolerability, and provide high-quality clinical evidence of long-term pharmacotherapy weight management specifically for the Chinese population with overweight or obesity. The Company plans to submit mazdutide's first NDA for weight management in the near term, and will also progress the development of mazdutide for other indications on the basis of scientific evidence and unmet medical needs. The Company will continue to strategically build our innovative next-generation product pipeline in the cardiovascular and metabolic (CVM) field, and help people's pursuit of a healthy life.

About Mazdutide (IBI-362)

The Company entered into an exclusive license agreement with Eli Lilly and Company 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, in addition to the effects of GLP-1R 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 robust weight loss and glucose-lowering effects in clinical studies, as well as multiple cardio-metabolic benefits including reducing waist circumference, blood lipids, blood pressure, blood uric acid, liver enzymes, liver fat content and improving insulin sensitivity. Currently, four Phase 3 studies of mazdutide in Chinese patients with overweight or obesity (GLORY-1 and GLORY-2) and type 2 diabetic (DREAMS-1 and DREAMS-2) subjects are underway, where GLORY-1 study has met the primary and all key secondary endpoints.

Cautionary Statement as required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that the Company will ultimately develop, market and/or commercialize IBI-362 successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

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

Hong Kong, China,
January 09, 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.

Reference:

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