



Uni-Bio Science Group’s Uni-GLP Developmental Potential in Treatment of COVID-19 and Other Indications

[18 September 2020 – Hong Kong] A fully integrated biopharmaceutical company – Uni-Bio Science Group Limited (the “Company”, together with its subsidiaries, the “Group”; Stock code: 00690.HK) is pleased to announce updates on the developmental potential of the Group’s innovative biologic self-developed drug Recombinant Exendin-4 Injection (“Uni-GLP”).

About Uni-GLP

Uni-GLP, a class of glucagon-like peptide-1 receptor agonists (“GLP-1 RAs”), can reduce high blood glucose by increasing insulin and decreasing glucagon secretion, is effective in the treatment of Type 2 diabetes mellitus (“T2DM”). GLP-1 RAs are particularly advantageous because of their incretin effect which can lower risk of hypoglycemia. In addition, GLP-1 RAs is one of the only classes of diabetic drugs shown to cause significant weight loss. The application for clinical trial of Uni-GLP submitted by the Company has been accepted by National Medical Products Administration (“NMPA”) on 14 July 2020. Currently, the Group’s professional and technical personnel are making great efforts to prepare for clinical trial-related works.

New Progress and Opportunities of GLP-1 RAs

Based on new data presented in the scientific community, GLP-1 RAs can treat a wide range of high value

indications such as obesity, cardiovascular disease (“CVD”), nonalcoholic fatty liver disease (“NAFLD”) and nonalcoholic steatohepatitis (“NASH”), Alzheimer's disease (“AD”), as well as new coronavirus disease 2019 (“COVID-19”; caused by severe acute respiratory syndrome coronavirus 2, “SARS-CoV-2”), where there are significant unmet medical needs.

As obesity is a common comorbidity of T2DM, this class is effective in T2DM patients who are overweight, accounting for at least 30% of all diabetes patients in the PRC according to IMS primary research. In addition, GLP-1 RAs has further been shown to have beneficial impact on cardiovascular function independent of its role in peripheral glycemic control, through increasing myocardial glucose uptake, preserving myocardial function following ischemic injury. Moreover, evidence suggests that GLP-1 secretion is impaired in patients with NAFLD and NASH-the aggressive form of NAFLD that can lead to cirrhosis and hepatocellular carcinoma, highlighting the role of GLP-1 RAs as potential candidates for NAFLD treatment. Furthermore, emerging evidences have shown that AD, caused by “starvation” of the brain, is associated with insulin resistance. When the brain cannot use glucose due to insulin resistance, it can lead to inflammation and deposition of plaques and tangles. Nevertheless, GLP-1 RAs can prevent the decline of brain glucose consumption, causing synaptogenesis and neurogenesis, thereby improving memory behavior.

Most recently, it has been hypothesized that GLP-1 RAs have been considered excellent candidates for the treatment of patients with COVID-19 with or without T2DM owing to their multiple beneficial effects on excessive inflammation-induced acute lung injury. Multiple preclinical studies performed in mice and rats with experimental induced lung injury demonstrated that GLP-1 RAs attenuate pulmonary inflammation, through inhibitory activity on cytokine release, as a result of their interference with nuclear factor- κ B (“NF- κ B”) signaling pathways. More recently, several studies have demonstrated the capacity of GLP-1 RAs to enhance the activity of the angiotensin converting enzyme 2 (“ACE2”) \rightarrow angiotensin (1-7) (“A(1-7)”) \rightarrow Mas

receptor (“MasR”) axis by directly stimulating ACE2 expression would contribute to reduce the progression of inflammatory and thrombotic processes frequently associated with the poor prognosis of SARS-CoV-2 infection, through the fostering of an antithrombotic and anti-inflammatory milieu. Lung injury and inflammation is seen in more severe COVID-19 infected patients, and a leading cause of COVID-19 related fatalities. The advantage compared with vaccine is that the GLP-1 RAs can continue to protect lung function even when coronavirus mutates.

Next Steps for Uni-GLP

The Board is optimistic about Uni-GLP’s potential in new therapeutic areas. The Group has already kicked off partnerships with several universities in PRC to conduct preclinical research of Uni-GLP in obesity, as well as to formulate a new innovative oral or 3rd generation Uni-GLP. Armed with the recent data of GLP-1 RA in treatment of CVD, NAFLD, NASH, AD and COVID-19, the Group is currently in talks with NMPA and prospective partners to expand Uni-GLP into these new areas.

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关于Uni-GLP

Uni-GLP, a GLP-1 agonist, is a non-insulin treatment candidate that stimulates the incretin pathway and is effective in the treatment of Type 2 diabetes.

GLP-1 agonist is also one of the only classes of diabetic drugs shown to also cause weight loss. As obesity is a common comorbidity of T2DM, this class is effective in T2DM patients who are overweight, accounting for at least 30% of all diabetes patients in the PRC according to IMS primary research. Moreover, this class of drugs also has other beneficial effects that are expected to drive physician prescription, such as lowering the risk of hypoglycemia and promoting β -cell regeneration, an important clinical advantage in managing Type 2 diabetes complications in the long term.

Clinical studies have shown that Uni-GLP effectively regulates blood glucose levels through multiple mechanisms including stimulating insulin secretion, inhibiting glucagon release, decreasing appetite and decreasing gastric emptying. It is positioned as a major second-line treatment option. The results from the Uni-GLP phase III trial demonstrate that, when compared to insulin glargine, Uni-GLP can effectively decrease the body weight of diabetes patients through suppressing the appetite and prolonging gastrointestinal emptying time.

It has to be mentioned that Uni-GLP is biologically expressed, with much closer physical structure to naturally produced GLP-1, giving it a stronger affinity to GLP-1 receptor and better stability profile; in clinical studies, Uni-GLP is shown to have better bioactivity and potential hypoglycemic effect with much lower immunogenicity. In addition, biological-expressed GLP-1 has a greener and lower production cost than the chemical synthetic one. Uni-GLP as short acting GLP-1 has more advantages against long-acting one, it has a much stronger efficacy on decreasing postprandial glucose, which accounts for >47% of newly diagnosed diabetes patient. Short-acting GLP-1 has a flexible administration regimen, which is also advantageous to newly diagnosed patient where time is needed to find a suitable dosage.

To offer a more patient-friendly product, Uni-GLP utilizes Un-Bio Science's R&D platform to develop next generation innovative formulations. Uni-GLP's 1st generation product is a next-generation liquid pre-filled injection pen, expected to be launched in 2022. The Group is also in the process of developing innovative formulations and drug delivery devices for Uni-GLP to expand the value of the product offering by increasing compliance and convenience to users in both the short and long-term.

Our clinical development team is also reviewing the potential to develop Uni-GLP in new indications and explore the other reported treatment targets, such as obesity and Alzheimer's disease, where there are also significant unmet medical needs.

Uni-GLP's potential as a new treatment has been recognised through the selection of Uni-GLP as a "New Key Drug Formulation" of the "State's Major Science and Technology Project under the 'Eleventh Five-Year Plan'". Uni-GLP was also awarded the "Specialty Contract of the State's Major Science and Technology Project" by the Ministry of Science and Technology of the People's Republic of China.

About Uni-Bio Science Group

Uni-Bio Science Group Limited is principally engaged in the research and development, manufacture and distribution of biopharmaceutical products. The research and development center is fully equipped with a complete system for the development of genetically-engineered products with a pilot plant test base which is in line with NMPA requirements. The Group has two GMP manufacturing bases in Beijing and Shenzhen. The Group also has a highly efficient commercialization platform and marketing network. The Group focuses on the development of novel treatments and innovative drugs addressing the therapeutic areas of endocrine as diabetes and osteoporosis, ophthalmology and dermatology. Please visit the official website of Uni-Bio Science Group for more information: www.uni-bioscience.com/

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