**Press Release (for immediate release)**

**China FDA Approves New Once-Weekly Bydureon® to Improve Glycemic Control in Patients with Type-2 Diabetes**

**Bydureon is the first and only approved glucagon-like peptide-1 (GLP-1) receptor agonist in China to be administered once-weekly**

January 3, 2018, Shanghai, 3Sbio Inc. (01530.HK) announced today that China's first Glucagon-like peptide-1 (GLP-1) receptor agonist weekly preparation Bydureon® (generic name Exenatide Microsphere for injection) has been formally approved by China Food and Drug Administration (CFDA), as a new treatment option to improve glycemic control for patients with type 2 diabetes.

As the first and currently the only GLP-1 medicine in China to be administered once-weekly, exenatide microsphere can reduce the frequency of dosing, reduce gastrointestinal adverse effects and increase drug stability and improve patient compliance by continuing to provide steady-state levels of exenatide with sustained release microsphere technology, which will provide a new treatment option for the majority of patients with type 2 diabetes in China.

At present, the GLP-1 receptor agonist weekly preparation has been launched in markets such as the United States, Europe, Japan, South Korea, Hong Kong and Taiwan, and has good safety as demonstrated in the clinical experience for patients with type 2 diabetes.

**China's diabetes management faces enormous challenges**

With the social and economic development and change in people's lifestyle, diabetes is increasingly becoming a global chronic disease that poses serious threats to human health, the prevalence rate of which in China is rapidly rising throughout the world. The incidence of diabetes in our country is even soaring, the affected population has reached 114 million, and showed a trend of development in younger patients. China has become "the world's largest diabetes country".

According to the data of epidemiological investigation of diabetes in China posted by JAMA in 2017, the latest prevalence rates of diabetes and pre-diabetes in our country were 10.9% and 35.7%. Among patients receiving hypoglycaemic therapy, blood glucose compliance rate is only 49.2％. How to effectively control blood sugar and improve the life quality of patients has become an important challenge to the contemporary clinical medicine.

**Improve glycemic control of type 2 diabetes once- weekly, thus enhancing compliance**

People's Hospital of Peking University Professor Ji Linong, chief researcher of Asia clinical research on Exenatide Microsphere phase III, China area leader of cardiovascular safety research (EXSCEL research) indicated that there are many reasons for poor blood glucose control, among others, multiple administrations, pain in the injection, which will greatly reduce long-term dependence on medicine of patients, while reduce the efficacy of the drug. The launch of GLP-1 receptor agonist once-weekly preparation in China will bring an extended treatment option for diabetics and is expected to further improve the control rate of patients with type 2 diabetes in China.

Clinical trials showed that Exenatide Microsphere can reduce glycosylated hemoglobin (HbA1c) 1.3%-1.9% once-weekly, reduce weight 2.0kg-3.7kg, which serves multiple purpose for hypoglycemic and weight loss, greatly improves the life quality of patients with diabetes. In addition, the relevant trials showed that taking Exenatide Microsphere once-weekly can reduce the patient's systolic blood pressure and blood lipid level, and significantly reduce risk of all-cause mortality, with good safety.

Professor Ji Linong said that Exenatide Microsphere is the first and currently the only new hypoglycemic drug in China to be administered once-weekly, the evidence of Asia clinical research on phase III showed that taking Exenatide Microsphere on the basis of oral hypoglycemic drugs, compared with China launched Exenatide which is administered twice daily, can control blood glucose better, lower risk of hypoglycemia, and effect of weight loss is equivalent to Exenatide. In addition, among GLP-1 receptor agonist weekly preparations have been launched, Exenatide Microsphere is also currently the only GLP-1 receptor agonist weekly preparation proved for cardiovascular safety by the large clinical trials(EXSCEL research).The results of this study provide an evidence for the patients’long-term, safe use of Exenatide Microsphere to control the blood glucose.

In 2016, AstraZeneca entered a strategic collaboration with 3SBio Inc. for the rights to commercialise Bydureon and Byetta in China. Leon Wang, Executive Vice President, International Region and President of AstraZeneca China, said: “The prevalence of diabetes is escalating rapidly in China, now estimated at 114 million people. As a company that puts patients first by developing innovative medicines, we are delighted to offer Exenatide Microsphere as the first and only in a new class of once-weekly injectable medicines to address unmet needs for patients with type-2 diabetes in China.”

Dr. LOU Jing, Chairman of 3S Pharmaceutical Group, said: "We are happy to see that Exenatide Microsphere, once-weekly new hypoglycemic drug, is approved, which will provide more choices for China's vast number of diabetics, and it’s also an important milestone for the strategic cooperation of 3SBio and AstraZeneca. I believe that we can bring this product to more patients with type-2 diabetes with 3SBio’s excellent marketing team and rich experience in the local market, and help them to carry out more effective diabetes management, thus improving their health level and life quality."

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**About Bydureon®**

Bydureon® (generic name Exenatide Microspheres for injection) is the first once-weekly hypoglycemic drug launched in China, which is used to improve glycemic control of type 2 diabetes and applicable to the patients not achieving satisfied level of glycemic control in case of taking metformin or sulfonylureas alone and taking metformin and sulfonylureas together. The medicine makes glucagon-like peptide-1 (GLP-1) receptor agonist exenatide, slow release in the body to play long-term hypoglycemic effect by the microsphere technique, it can be administered once-weekly, 2 mg each time. The patient can be dosed at any time of the day, regardless of meal or not. Bydureon® has been proved by the studies of DURATION series to provide HbA1c reduction of 1.3~1.9% and weight reduction of 2.0kg-3.7kg with once-week administration. The launch of Bydureon® will provide better choice of medicines for diabetics in China.

**About 3S Pharmaceutical Group**

3S Pharmaceutical Group is a leading bio-pharmaceutical company integrating R&D, production and sales, with a focus on improving the life quality of patients with high-quality medicines to benefit human health. At present, the Group owns more than 80 national invention patents and has launched more than 30 kinds of products into the market, covering several treatment fields, among others, cancer, autoimmune, kidney disease, metabolism and dermatology. The Group owns 4 R&D centers of the National Engineering Research Center of Antibody Medicine and dual platforms for biopharmaceutical and chemical medicine. There are 25 kinds of products under R&D, 16 kinds of them are under R&D as the national first-class new drugs. The Group also owns 6 production bases complying with GMP standards. In the future, 3S Pharmaceutical Group will continue to uphold the concept of “Care for Life, Cherish Life, Create Life” to create a world's leading bio-pharmaceutical company in China.

Reference materials:

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# 3. [Efficacy and safety of exenatide once-weekly vs exenatide twice-daily in Asian patients with type 2 diabetes mellitus.](https://www.ncbi.nlm.nih.gov/pubmed/24843631) Ji L, Onishi Y, Ahn CW, Agarwal P, Chou CW, Haber H, Guerrettaz K, Boardman MK. J Diabetes Investig. 2013 Jan 29;4(1):53-61. doi: 10.1111/j.2040-1124.2012.00238.x. Epub 2012 Sep 14.PMID:24843631

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