Shionogi Receives Marketing and Manufacturing Approval of a Drug for Lipodystrophy, "METRELEPTIN for Subcutaneous Injection 11.25 mg 'SHIONOGI'"

Osaka, Japan, March 25, 2013 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that it received marketing and manufacturing approval of recombinant human leptin, "METRELEPTIN for subcutaneous injection 11.25 mg 'SHIONOGI'" (generic name: metreleptin) for lipodystrophy on March 25, 2013 in Japan. Metreleptin was in-licensed by Shionogi from US-based Amylin Pharmaceuticals, LLC., a subsidiary of Bristol-Myers Squibb Company currently.

Lipodystrophy is a rare and life-threatening disorder characterized by a lack of the subcutaneous fat tissue required for normal metabolic function, and is highly correlated to metabolic abnormalities such as severe diabetes, hypertriglyceridemia and fatty liver disease. There are currently no effective therapies that treat the underlying cause of the disease. Meanwhile, clinical investigation by the National Institutes of Health and the Department of Medicine and Clinical Science at the Kyoto University Graduate School of Medicine have recently shown that lipodystrophy is associated with leptin deficiency, and that leptin therapy is effective in treating diabetes, hypertriglyceridemia and fatty liver disease associated with lipodystrophy.

The Department of Medicine and Clinical Science at the Kyoto University Graduate School of Medicine, a research center of the Special Research Initiation for Drug Discovery for Intractable Diseases, and with assistance from the Translational Research Center at Kyoto University Hospital, conducted an investigator-initiated trial using metreleptin as a potential treatment for lipodystrophy patients. In July 2012, Shionogi filed an NDA with Japanese Ministry of Health, Labor and Welfare for metreleptin based on the results of the trial, and then, received an approval for the treatment of lipodystrophy now.

Shionogi expects to make contributions to the treatment of lipodystrophy through the supply of this recombinant human leptin orphan drug, and will continue to strive to accomplish the missions of a pharmaceutical company to improve QOL of patients and their families who suffer from other rare intractable diseases.

About Lipodystrophy

Lipodystrophy is a rare and life-threatening disorder characterized by a lack of the required subcutaneous fat tissue necessary for normal metabolic function throughout the whole body or in certain parts of the body, and is highly correlated to metabolic abnormalities such as diabetes and severe insulin resistance, hypertriglyceridemia and fatty liver disease. It is known that common treatments for diabetes and hyperlipidemia alone are not effective for this disease.

About Leptin

Leptin is a hormone secreted by fat tissue, which triggers the hypothalamus to suppress appetite. It is also known that leptin improves insulin resistance, glucose metabolism and lipid metabolism.

Product Overview

Product Name:	METRELEPTIN for subcutaneous injection 11.25 mg 'SHIONOGI'
Generic Name:	Metreleptin (Genetical Recombination)
Indication:	Lipodystrophy
Form and Content:	Parenteral injection including 11.25 mg of metreleptin (genetic recombination) in a vial
Dosage and Administration:	In general, the dose of 0.04 mg/kg as metreleptin is to be administered subcutaneously to male patients once daily. A single daily dose to female patients is 0.06 mg/kg for women under the age of 18 and 0.08 mg/kg for women aged 18 or over. The dosage is initiated from the doses of 0.02, 0.03 and 0.04 mg/kg, respectively, and increased by each general dose described above within about a month. The dosage should be decreased according to the medical condition of patients.
Approval Date:	March 25, 2013

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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