

Shionogi Filed a New Drug Application for Recombinant Human Leptin for Lipodystrophy

Osaka, Japan, August 1, 2012 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that Shionogi filed a new drug application (NDA) with the Japanese Ministry of Health, Labor and Welfare for recombinant human leptin (generic name: metreleptin) for lipodystrophy in July 2012. Metreleptin was in-licensed by Shionogi from US-based Amylin Pharmaceuticals, Inc.

Lipodystrophy is a rare and life-threatening disorder characterized by a lack of required fat tissue 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.

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.

Recently, 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 shown that lipodystrophy is associated with leptin deficiency, and that leptin-replacement therapy is effective in treating diabetes, hypertriglyceridemia and fatty liver disease associated with lipodystrophy.

Therefore, 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 leptin-replacement therapy for lipodystrophy patients. The trial has concluded and, in July 2012, Shionogi filed an NDA for metreleptin for the treatment of lipodystrophy based on the results of the trial.

If approved by regulators, Shionogi will strive to make contributions to the treatment of lipodystrophy through the stable supply of this recombinant human leptin orphan drug.

About Lipodystrophy

Lipodystrophy is a rare and life-threatening disorder characterized by a lack of required fat tissue 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 are not effective for this disease.

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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