

News Release

Approval of an Additional Indication of Combination Therapy of Glufast[®] and Insulin Sensitizer in Japan

Matsumoto, Japan & Osaka, Japan, February 24, 2009 --- Kissei Pharmaceutical Co., Ltd (President, C.E.O. Mutsuo Kanzawa, "Kissei") and Takeda Pharmaceutical Company Limited (President, Yasuchika Hasegawa, "Takeda") announced today that an additional indication of "combination therapy with insulin sensitizer" for Glufast[®] (generic name: mitiglinide) 5mg tablet and 10mg tablet, which is being co-marketed by Kissei and Takeda, was approved by the regulatory authorities in Japan.

Glufast, originally created and developed by Kissei, co-marketed in tandem with Takeda in Japan since May 2004, is a diabetic medicine that promotes insulin secretion by stimulating the pancreatic β -cells. It demonstrates effects promptly after dosing, thereby it brings insulin secretion closer to its natural patterns and improves postprandial hyperglycemia. Because of its duration of action, Glufast is less liable to trigger hypoglycemia.

Insulin-resistance is a condition where the body does not effectively use the insulin it produces, and pioglitazone HCl, which is insulin sensitizer discovered and marketed by Takeda, is available in Japan under the tradename Actos[®]. Actos suppresses the production of the glucose in the liver while improving the sensitivity to insulin in the peripheral tissues.

In the randomized, double-blind, controlled comparative study, in which clinical usefulness of Actos monotherapy and that of Glufast/Actos combination therapy were evaluated, the latter showed a statistically significant difference in improving HbA1c that is an indicator of plasma glucose control, without increasing the risk of hypoglycemia.

In addition, the findings from this combination therapy showed an improvement of glucose spike, a sharp rise in blood glucose following a meal which is a risk factor for atherosclerosis, and subsequently for cardiovascular risks such as myocardial infarction. Therefore, it is expected that this combination therapy could be a potential therapy for such risks.

With this additional indication of combination therapy of Glufast/Actos, it becomes feasible to pursue better control of plasma glucose, providing further treatment options for patients with type 2 diabetes and physicians who treat them.

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