News Release

Kissei Pharmaceutical Co., Ltd.
Takeda Pharmaceutical Company Limited

Approval of Partial Changes of Indication of Glufast® in Japan

Matsumoto, Japan and Osaka, Japan, September 13, 2013 --- Kissei Pharmaceutical Co., Ltd (President & CEO: Mutsuo Kanzawa, “Kissei”) and Takeda Pharmaceutical Company Limited (President & CEO: Yasuchika Hasegawa, “Takeda”) announced today the approval of an application for partial changes of indication of Glufast® (generic name: mitiglinide) 5 mg tablet and 10 mg tablet, which is being co-marketed by Kissei and Takeda, by the Ministry of Health, Labour and Welfare (MHLW) in Japan. The newly approved indication is "Type 2 Diabetes" which now allows concomitant therapy of Glufast with all the oral anti-diabetic agents except sulfonylureas.

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

In the treatment of Type 2 Diabetes, medication is administered to patients with inadequate glycemic control despite diet therapy and/or exercise therapy. Type 2 diabetes is a chronic and progressive disease. In some cases, monotherapy using oral hypoglycemic agents does not deliver the desired treatment outcome. In many other cases, despite good initial glycemic control, reversion to poor control occurs during the course of the treatment. In such cases, combination therapy is practiced, with the introduction of another agent with a different mechanism of action.

Taking into consideration these clinical practices and needs, and also aiming to evaluate the potential benefits of Glufast in concomitant therapy settings, Kissei conducted a long-term combination therapy trial in type 2 diabetic patients with inadequate glycemic control after monotherapy of dipeptidyl peptidase IV (DPP-IV) inhibitors or biguanide in accordance with the Guideline for Clinical Evaluation of Oral Hypoglycemic Agents of the MHLW. The trial involved the concomitant therapy of Glufast with a biguanide or a DPP-IV inhibitor which was not a part of approved indications.

The results of the trial demonstrated that the concomitant therapy of Glufast with either one of the above-mentioned agents resulted in the improvement of postprandial hyperglycemia over the long-term without increased risk of hypoglycemia, and also significantly improved the HbAlc value which is an indicator of overall glycemic control. These results confirmed the benefits of all the potential concomitant

therapies in clinical practice of Glufast with other types of oral hypoglycaemic agents, except sulfonylureas, and accordingly, an indication of "Type 2 Diabetes" for Glufast was approved by the MHLW in Japan.
Both parties are pleased with the approval of this new indication which covers a wider range of concomitant therapies of Glufast, and we expect that this product will further help achieve and maintain glycemic control and prevent complications in patients with type 2 diabetes.

< Reference >

Indication of Glufast

Before Indication Change	After Indication Change
Improvement of postprandial glycemic level in patients with type 2 diabetes In patients inadequately glycemic controlled by following treatments, 1. Treatment of diet therapy and exercise only 2. In addition to treatment by diet and exercise, treatment by alpha-glucosidase inhibitor 3. In addition to treatment by diet and exercise, treatment by thiazolidinediones	Type 2 diabetes

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