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ONO PHARMACEUTICAL CO., LTD.

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Launch of a Type 2 Oral Antidiabetic Drug, GLACTIV® Tablet

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced that a type 2 oral antidiabetic drug, GLACTIV® Tablet 25 mg, GLACTIV® Tablet 50 mg, and GLACTIV® Tablet 100 mg (INN: sitagliptin phosphate hydrate) was launched in Japan today.

The drug was jointly developed by Ono and Banyu Pharmaceutical Co., Ltd. (Tokyo, Japan, hereinafter "Banyu") in Japan, based on the license agreement concluded between Ono and Merck & Co., Inc., Whitehouse Station N.J. U.S.A. (through an affiliate) in November 2004, and was approved for marketing on October 16, 2009.

Type 2 diabetes mellitus is metabolic disorder, mainly marked by chronic hyperglycemia resulting from inadequate insulin production/secretion, insufficient function of produced insulin, or glucose excessively produced by the body. The number of diabetic patients tends to increase every year. A recent survey reports that approximately 8.9 million Japanese were strongly suspected of diabetes.

GLACTIV® is a highly selective dipeptidyl peptidase 4 (DPP-4) inhibitor, which was originally discovered by Merck & Co., Inc., Whitehouse Station N.J. U.S.A., and which enhances a natural body system called the incretin system, to help regulate blood sugar. Incretins are hormones released by the gut to control the body's glucose levels. When blood sugar is elevated, incretins released from the gut work to help the body regulate high blood sugar levels and to release less glucagon, thereby signalling the liver to reduce its production of glucose. GLACTIV® is an oral antidiabetic drug to exert hypoglycemic effect with the novel mechanism of action by inhibiting DPP-4, an enzyme which metabolites incretins, and thereby enhance the body's own ability to regulate blood sugar levels by increasing levels of incretin hormones in a glucose dependent manner thereby helping to decrease blood sugar levels in patients with type 2 diabetes. GLACTIV® can be administered once a day, either before or after eating because no food effect is observed.

The drug was launched as the world's first DPP-4 inhibitor by Merck & Co., Inc., Whitehouse Station N.J. U.S.A. in August 2006. It is now approved in more than 85 countries in the world and has been prescribed to more than 18 million patients in the US alone.

Note: Banyu, a co-marketing partner in Japan, will sell the drug under the product name of Januvia® Tablet 25 mg, Januvia® Tablet 50 mg, and Januvia® Tablet 100 mg.

PRODUCT SUMMARY:

Product Name	GLACTIV® Tablet 25 mg, GLACTIV® Tablet 50 mg, GLACTIV® Tablet 100 mg
Generic Name (INN)	Sitagliptin phosphate hydrate
Indication	Type 2 diabetes mellitus; Sitagliptin should be used only in patients who do not sufficiently respond to any one of the following treatments. 1. Dietary therapy and/or exercise therapy only 2. Use of sulfonylureas in addition to dietary therapy and/or exercise therapy 3. Use of thiazolidinediones in addition to dietary therapy and/or exercise therapy 4. Use of biguanides in addition to dietary therapy and/or exercise therapy
Dosage and Administration	Usually, for adults, 50 mg of sitagliptin is orally administrated once daily. While the clinical course is being closely observed, if the effect is insufficient, the dosage can be increased up to 100 mg once daily.
Product Characteristics	1. GLACTIV® is the first selective dipeptidyl peptidase 4 (DPP-4) inhibitor in Japan. 2. Once a day treatment with GLACTIV® improves HbA1c, post prandial hyperglycemic state and fasting plasma glucose. GLACTIV® can be administered once a day, either before or after eating because no food effect is observed. 3. GLACTIV® improves glycemic control even when diet and exercise, which are base treatments for type II diabetes, in combination with a sulphonylurea, a thiazolidinedione or a biguanide do not provide adequate glycemic control. 4. GLACTIV® provides stable improvement of glycemic control for 52 weeks. 5. Adverse reactions were observed in 96 (8.1%) out of 1,190 patients studied in the clinical trials performed in Japan, and those include, but not limited to, hypoglycemia in 17 patients (1.4%), constipation in 12 patients (1.0%). Abnormalities in laboratory testing, causal relation to which cannot be denied, were observed in 49 (4.1%) out of 1,188 patients, and those include, but not limited to, elevation of ALT in 18 patients (1.5%), elevation of AST in 12 patients (1.0%) and elevation of gamma GPT in 10 patients (0.8%).
Packaging:	GLACTIV® Tablet 25mg: 100 tablets (blister packaging and bottle) 420 tablets (blister packaging) 500 tablets (blister packaging) GLACTIV® Tablet 50mg: 100 tablets (blister packaging and bottle) 420 tablets (blister packaging) 500 tablets (blister packaging and bottle) GLACTIV® Tablet 100mg: 100 tablets (blister packaging and bottle) 420 tablets (blister packaging) 500 tablets (blister packaging and bottle)

NHI reimbursement prices	GLACTIV® Tablet 25mg:	JPY 99.50
	GLACTIV® Tablet 50mg:	JPY 185.70
	GLACTIV® Tablet 100mg:	JPY 278.60

Date of NHI price listed: December 11, 2009
Date of launch: December 11, 2009