

FOR IMMEDIATE RELEASE

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Launch of Onglyza® Tablets 2.5mg, 5mg for Type 2 Diabetes

Tokyo, Japan, July 8, 2013—Kyowa Hakko Kirin Co., Ltd. (President and CEO: Nobuo Hanai; “Kyowa Hakko Kirin”) announced today that it will launch Onglyza® Tablets 2.5mg and 5mg (generic name: saxagliptin hydrate; referred to below as “Onglyza®”) to treat type 2 diabetes in Japan July 9, 2013.

Onglyza® was originated by Bristol-Myers Squibb. This oral hypoglycemic agent for diabetes acts by selectively inhibiting dipeptidyl peptidase-4 (DPP-4), an enzyme that breaks down glucagon-like peptide-1 (GLP-1^{*1}) and gastric inhibitory peptide^{*2} (GIP). Once-daily dosing with 5mg of Onglyza® produces a blood glucose-dependent reduction in blood sugar levels. The efficacy and safety of Onglyza® were confirmed in clinical studies performed in accordance with the Guideline for Clinical Evaluation of Oral Hypoglycemic Agents (PFSB/ELD Notification No. 0709-1, July 9, 2010). Onglyza® can be administered in combination with existing oral hypoglycemic agents, such as sulfonylurea drugs, thiazolidines, biguanides, short-acting insulin secretagogues, and alpha-glucosidase inhibitors. Combination use of Onglyza® with insulin preparations is also included in the approved indication of type 2 diabetes.

Onglyza® provides a new option in the treatment of type 2 diabetes and is therefore expected to help healthcare professionals and patients to manage type 2 diabetes.

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※1

GLP-1 is secreted soon after eating, stimulating the pancreatic beta cells and increasing insulin secretion. When DPP-4 is inhibited, blood levels of GLP-1 are maintained and rising blood sugar levels can be curbed.

※2

Gastric inhibitory peptide (GIP) is a GI hormone found in the mucosa of the small intestine. Release of the hormone, mediated by the presence of glucose or fatty acids in the duodenum, results in the release of insulin by the pancreas and inhibition of gastric mobility acid secretion.



Onglyza® product overview

Product name	Onglyza® Tablets 2.5 mg and 5 mg
Generic name	Saxagliptin hydrate
Indication	Type 2 diabetes
Dosage and Administration	Once-daily oral administration of 5 mg saxagliptin in adults. Once-daily oral administration of 2.5 mg is also possible, based on the condition of the individual patient.
Approval Date	March 25, 2013
Date of NHI Drug Price Listing	May 24, 2013
Drug price	¥110.2/2.5mg tablet, ¥166.0/5mg tablet

For further information please access: http://www.kyowa-kirin.com/news_releases/index.html