

**FOR IMMEDIATE RELEASE**

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**Completion of Drug Price Listing and Marketing Authorization Transfer of Onglyza<sup>®</sup> Tablets 2.5mg, 5mg for Type 2 Diabetes**

Tokyo, Japan, May 24, 2013—Kyowa Hakko Kirin Co., Ltd. (President and CEO: Nobuo Hanai; “Kyowa Hakko Kirin”) today announced that Onglyza<sup>®</sup> was listed on the National Health Insurance (NHI) drug price list on May 24, 2013, and that on May 8, 2013 Kyowa Hakko Kirin took over the marketing authorization for Onglyza<sup>®</sup> Tablets 2.5mg and 5mg (generic name: saxagliptin hydrate; referred to below as “Onglyza<sup>®</sup>”) to treat type 2 diabetes from Otsuka Pharmaceutical Co., Ltd. (President and CEO: Taro Iwamoto; “Otsuka”) after marketing authorization was granted to Otsuka in March 2013.

Onglyza<sup>®</sup> 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 (GIP). Once-daily dosing with Onglyza<sup>®</sup> produces a blood glucose-dependent reduction in blood sugar levels. The efficacy and safety of Onglyza<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> with insulin preparations is also included in the approved indication of type 2 diabetes.

Kyowa Hakko Kirin is preparing to launch Onglyza<sup>®</sup> now that the drug has been listed on the NHI drug price list.

Onglyza<sup>®</sup> 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.



Onglyza<sup>®</sup> product overview

Product name	Onglyza <sup>®</sup> 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
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](http://www.kyowa-kirin.com/news_releases/index.html)