



March 25, 2013

#### For Immediate Release

Company name Otsuka Holdings Co., Ltd.

Representative Tatsuo Higuchi

President and Representative Director, CEO

Code number 4578 First Section , Tokyo Stock Exchange

Inquiries Takuma Kimura

Director, Investors Relations Department

## Otsuka Obtains Marketing Approval in Japan

# for Onglyza® Tablets to Treat Type 2 Diabetes; Transferred Rights to Kyowa Hakko Kirin

Otsuka Pharmaceutical Co. Ltd., a subsidiary of Otsuka Holdings Co., Ltd., and Kyowa Hakko Kirin Co., Ltd. today announced that Otsuka has obtained marketing approval for Onglyza<sup>®</sup> 2.5mg and 5mg Tablets (generic name: saxagliptin hydrate) to treat type 2 diabetes. Otsuka signed an agreement with Kyowa Hakko Kirin in June 26, 2012, transferring to Kyowa Hakko Kirin the exclusive development and marketing rights for Onglyza<sup>®</sup> in Japan.

The consolidated business forecast of fiscal 2012 announced by Otsuka Holdings on May 11, 2012 will not be changed.

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Tokyo, Japan, March 29, 2013—Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Kyowa Hakko Kirin Co., Ltd.(Kyowa Hakko Kirin) today announced that Otsuka has obtained marketing approval for Onglyza<sup>®</sup> Tablets 2.5mg and 5mg(generic name: saxagliptin hydrate) to treat type 2 diabetes. Otsuka signed an agreement with Kyowa Hakko Kirin in June 2012, transferring to Kyowa Hakko Kirin the exclusive development and marketing rights for Onglyza<sup>®</sup> in Japan.

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<sup>\*1</sup>) 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® were confirmed in accordance with the Guideline for Clinical Evaluation of Oral Hypoglycemic Agents (PFSB/ELD Notification No. 0709-1, July 9, 2010).

Onglyza® has been approved in 85 countries, including the US and EU (as of February 2013).

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<sup>\*1</sup> 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.

Otsuka Pharmaceutical is to transfer marketing rights in Japan for Onglyza<sup>®</sup> to Kyowa Hakko Kirin, based on the 2012 agreement signed by the two companies. Otsuka will receive ¥8.2 billion from Kyowa Hakko Kirin upon approval, in addition to the initial payment of ¥3.0 billion. Moreover, Otsuka will receive running royalties after the launch of the drug in proportion to its revenue.

The approval of 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.

## Onglyza® 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