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FOR IMMEDIATE RELEASE

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**Glactiv® has received approval
for the additional indication of combination use with insulin**

Ono Pharmaceutical Co., Ltd. ("Ono") announced today that Glactiv® (generic name: sitagliptin phosphate hydrate), an oral type-2 diabetes drug, has as of September 16, 2011 received approval for the additional indication of combination use with insulin products, the application for which was submitted in October 2010.

Glactiv® was launched in December 2009 as the first DPP-4 (dipeptidyl peptidase-4) inhibitor in Japan. This drug, when administered once daily, selectively inhibits DPP-4, increases active incretin levels, and consequently enhances glucose-dependent insulin secretion to exert the hypoglycemic effect. This drug is not affected by food, and thus can be administered either before or after a meal.

Insulin products are widely used by patients with advanced type-2 diabetes. This approval, which will make available combination therapy with Glactiv® and insulin products, can provide more diabetes treatment options.

Ono will actively provide information for proper use of Glactiv® and its higher evaluation, and contribute to diabetes treatment in Japan.

Shown below is the new set of indications of Glactiv® effected by this approval.

(The newly approved indication is shown in bold type and underline.)

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
- 5) Use of α -glucosidase inhibitors in addition to dietary therapy and/or exercise therapy
- 6) **Use of insulin in addition to dietary therapy and/or exercise therapy**



<Reference>

Sitagliptin was co-developed for the Japanese market by Ono and Banyu Pharmaceutical Co., Ltd. (presently MSD) under the licensing agreement signed by Ono and Merck & Co., Inc., Whitehouse Station, N.J., U.S.A. in November 2004.

Glactiv[®] (Ono) and Januvia[®] (MSD) are the first selective DPP-4 (dipeptidyl peptidase-4) inhibitor launched in Japan.

Sitagliptin was launched in 2006 as the world's first DPP-4 inhibitor in Mexico by Merck & Co., Inc., and has been approved in at least 98 countries with at least 20 million prescriptions dispensed.