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FOR IMMEDIATE RELEASE

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**Ono and MSD Submit Additional Indication Application for  
Sitagliptin Combination Therapy with Insulin**

Ono Pharmaceutical Co., Ltd. ("Ono") and MSD K.K. ("MSD") announced today that an application for combination therapy with insulin drug products has been filed as an additional indication to the oral type-2 diabetes drug sitagliptin, which is marketed in Japan by both companies.

Insulin products are widely used by patients with advanced type 2 diabetes.

If the application is approved, combination therapy of sitagliptin with insulin products would provide expanded treatment options to patients and medical professionals.

Current approved indications for sitagliptin are as follows:

Type-2 diabete mellitus; Sitagliptin should be used only in patients who do not sufficiently respond to any one of the following therapies:

- (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

In addition, Ono and MSD also filed for an additional indication for combination therapy of sitagliptin with  $\alpha$ -glucosidase inhibitors in June 2010.

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<sup>®</sup> (Ono) and Januvia<sup>®</sup> (MSD) are the first selective DPP-4 (dipeptidyl peptidase-4) inhibitor launched in Japan and can be used in combination with the broadest variety of other oral anti-diabetic drugs. Sitagliptin was launched as the world's first DPP-4 inhibitor in Mexico by Merck & Co., Inc in 2006 and has been approved in more than 89 countries with more than 22 million prescriptions dispensed (as of June 2010) in the United States alone.

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