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FOR IMMEDIATE RELEASE

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**Ono and Banyu File Additional Indication Application for  
Type-2 Diabetes Drug Sitagliptin  
- Combination Therapy with  $\alpha$ -Glucosidase Inhibitors -**

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Ono Pharmaceutical Co., Ltd. ("Ono") and Banyu Pharmaceutical Co., Ltd. ("Banyu") announced today that an application for combination therapy with  $\alpha$ -glucosidase inhibitors has been filed as an additional indication to the oral treatment type-2 diabetes drug sitagliptin, which is being marketed in Japan by both companies .

Widely administered to type-2 diabetes patients in Japan,  $\alpha$  -glucosidase inhibitors reduce spikes in blood sugar after meals by slowing the digestive absorption of complex carbohydrates in the intestinal tract. If it becomes possible, a therapy combining sitagliptin with  $\alpha$  -glucosidase inhibitors, one of the most commonly prescribed oral diabetes medication in Japan, would offer a new treatment option.

The current approved indications for sitagliptin are as follows:

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

Sitagliptin was co-developed for the Japanese market by Ono and Banyu under the licensing agreement signed by Merck & Co., Inc., Whitehouse Station, N.J., U.S.A. and Ono in 2004. Glactin (Ono) and Januvia (Banyu) 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 patients dispensed in the United States alone.

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