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**Approval for Additional Indication Application of Type-2 Diabetes Drug, Glactiv[®] Tablets
- Combination Therapy with Alpha-glucosidase Inhibitors -**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced today that an application filed in June 2010 for combination therapy with alpha-glucosidase inhibitors was approved on May 20, 2011 as an additional indication to the oral treatment drug of type-2 diabetes, Glactiv[®] Tablets (generic name: sitagliptin).

Glactiv[®] Tablets is the first DPP-4 (a dipeptidyl-peptidase-4) inhibitor launched in Japan in December 2009. Once daily administration of the drug selectively inhibits DPP-4, and decreases blood sugar by increasing activated incretin and blood sugar dependently enhancing insulin secretion. No food effect was observed and therefore it can be taken either before or after a meal.

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. The approval this time allows Glactiv[®] Tablets to be taken together with many other oral type-2 diabetes drugs in addition to the single therapy with the drug, and offers medical professionals and the patients an additional treatment option for the treatment of type-2 diabetes. We will continue to promote the information providing activities so that Glactiv[®] Tablets can be used properly and highly appraised and contributes to the treatment of type-2 diabetes.

The following is the clinical indication of Glactiv[®] Tablets including the one approved this time, which is shown in boldface.

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 and/or exercise therapy only
2. Use of sulfonylureas in addition to dietary and/or exercise therapy
3. Use of thiazolidinediones in addition to dietary and/or exercise therapy
4. Use of biguanides in addition to dietary and/or exercise therapy
5. **Use of alpha-glucosidase inhibitors in addition to dietary and/or exercise therapy**

ADDITIONAL INFORMATION

Sitagliptin was co-developed for the Japanese market by Ono and Banyu Pharmaceutical Co., Ltd. (currently MSD K.K.) under the licensing agreement signed by Merck & Co., Inc., Whitehouse Station, N.J., U.S.A. and Ono in November 2004. The drug has been sold under the trade names of Glactiv[®] by Ono and Januvia[®] by MSD K.K..

Sitagliptin was launched as the world first DPP-4 inhibitor in Mexico by Merck & Co., Inc., Whitehouse Station, N.J., U.S.A. in 2006 and since then it has been approved in more than 95 countries with more than 20 million patients dispensed. Meanwhile Ono and MSD K.K. filed additional application for combination therapy with insulin in October 2010.