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**
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.