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**Glactiv[®] has obtained the approval of the partial change in
the indications of “type 2 diabetes”**

Ono Pharmaceutical Co., Ltd. (Head Office: Osaka City; President and Representative Director: Gyo Sagara; “Ono”) announced today that Glactiv[®] (generic name: sitagliptin phosphate hydrate), an oral type-2 diabetes drug, has obtained approval of a partial change in the indications of “type 2 diabetes”. This approval allows Glactiv[®] to be used in combination treatment with all oral medications for type 2 diabetes and insulin products.

Glactiv[®] was launched in December 2009 as the first DPP-4 (dipeptidyl peptidase-4) inhibitor in Japan. Once-daily administration of Glactiv[®] selectively inhibits DPP-4, increases active incretin levels, and exerts hypoglycemic effect in a glucose-dependent manner. Glactiv[®] was not indicated for the combination therapy with rapid-acting insulin secretagogues to treat type 2 diabetes until now. However, we applied for the partial change in the indications in August 2013 in response to the results obtained from studies of combination use of rapid-acting insulin secretagogues and Glactiv[®] based on “Guideline for Clinical Evaluation of Oral Hypoglycemic Agents”*

This approval allows Glactiv[®] to provide broader therapeutic options appropriate to patient’s clinical condition in monotherapy and combination therapy for treatment of type 2 diabetes.

Ono will make a contribution to treatment for diabetes in Japan by actively providing accurate information on proper use of Glactiv[®] to patients and healthcare professionals and enhance its reputation as an oral medication for type 2 diabetes.

****Guideline for Clinical Evaluation of Oral Hypoglycemic Agents****

A guideline published by Ministry of Health, Labor and Welfare in July 2010, to provide procedures for clinical evaluation for new drug application of oral hypoglycemic agents. Based on this guideline, the description of the indication is “type 2 diabetes” when an investigational drug is confirmed to be useful in clinical studies conducted with all oral hypoglycemic agents that are potentially combined with the investigational drug.

<Reference>

Sitagliptin was co-developed for the Japanese market by Ono and MSD K.K. (formerly Banyu Pharmaceutical Co., Ltd.; “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) were launched in December 2009 as the first DPP-4 (dipeptidyl peptidase-4) inhibitor in Japan.