

August 13, 2013

News Release

Ono Pharmaceutical Co., Ltd.  
MSD K.K.

**Ono Pharmaceutical and MSD applied for partial change in indications of “Sitagliptin”, to add “type 2 diabetes”**

Ono Pharmaceutical Co., Ltd. (Head office: Osaka City, President: Gyo Sagara, “Ono”) and MSD K.K. (Head office: Chiyoda-ku, Tokyo, President: Tony Alvarez, “MSD”) today applied for a partial change in the indications of “Sitagliptin”, an oral therapeutic drug for type 2 diabetes marketed in Japan by both companies, to add “type 2 diabetes.”

“Sitagliptin” had been approved for the combination with sulfonylureas (SUs), thiazolidines, biguanides, alpha-glucosidase inhibitors and insulin preparations in the combination therapy with existing therapeutic drugs for diabetes, but it was not indicated for the combination therapy with rapid-acting insulin secretagogues. However, we applied for a partial change in the indications based on “Guideline for Clinical Evaluation of Oral Hypoglycemic Agents”<sup>\*\*</sup> in response to the results of a study of “Sitagliptin” in combination with rapid-acting insulin secretagogues.

If the additional indication is approved through this application, “Sitagliptin” will be combined with all oral hypoglycemic agents and insulin preparations and provide broader therapeutic options to medical professionals and patients.

“Sitagliptin” was jointly developed in Japan by MSD (formerly Banyu Pharmaceutical Co., Ltd.) and Ono based on the license agreement concluded between Merck & Co., Inc., Whitehouse Station, N.J., U.S.A. and Ono in November 2004. It was launched in December 2009 as Januvia<sup>®</sup> from MSD and as Glactiv<sup>®</sup> from Ono as the first selective DPP-4 inhibitor in Japan. It is approved in more than 120 countries and regions overseas including the United States and European and Asian countries (as of June 2013).

<sup>\*\*</sup>“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.

### **About MSD**

Today's MSD is a global healthcare leader working to help the world be well. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.msd.co.jp](http://www.msd.co.jp)

### **About Ono**

Ono is a R&D-oriented pharmaceutical company specialized in creating innovative medicines in specific areas and is headquartered in Osaka, Japan.

For more information about Ono, visit the company's website at <http://www.ono.co.jp/eng/index.html>.

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