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Announcement of JNDA Submission in Japan for SITAGLIPTIN, a New Oral Treatment of Type II Diabetes

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President: Toshiharu Korekane) and Banyu Pharmaceutical Co., Ltd. (Tokyo, Japan, President: David W. Anstice) announced today that an application for marketing approval of SITAGLIPTIN phosphate monohydrate (Development Code: ONO-5435 / MK-0431), a new oral treatment for type II diabetes, has been submitted in Japan. The companies had jointly developed * the compound in Japan.

SITAGLIPTIN is a dipeptidyl-peptidase (DPP) 4 inhibitor, which is potentially a new class of oral drug for treatment of type II diabetes. The mechanism of action is distinct from any classes of glucose lowering agents currently available in the market.

When blood sugar is elevated, incretins, one of gastrointestinal hormones, work in two ways to help the body reduce high blood sugar levels; they trigger the pancreas to increase insulin and enhance glucose intake into tissues; and signal the liver to stop producing glucose by inhibiting glucagon secretion from the pancreas. SITAGLIPTIN enhances the incretin system, the ability of the body to reduce the elevated blood sugar (serum glucose) levels by inhibiting the DPP 4. the degradating enzyme of incretins and improves the hyperglycemic state of type II diabetes.

SITAGLIPTIN is developed by Merck & Co., Inc., Whitehouse Station, New Jersey, U.S.A. It has been approved in 58 countries and regions including the U.S. and countries of EU and marketed in 33 countries (as of October 22, 2007).

^{*:} The phase III clinical studies was jointly conducted by Ono and Banyu in Japan according to the provisions of the License Agreement entered between Merck & Co., Inc., Whitehouse Station, New Jersey, U.S.A. and Ono in November 2004.