

April 5, 2007

Ono Pharmaceutical Co., Ltd.  
Banyu Pharmaceutical Co., Ltd.

**Merck & Co, Inc. (Whitehouse Station, New Jersey, USA) Announced Approval of  
SITAGLIPTIN, a New Oral Treatment of Diabetes, in the European Union**

Merck & Co., Inc. (Whitehouse Station, New Jersey, USA) announced that SITAGLIPTIN, a new oral treatment of type II diabetes, that has been marketed by the company in the US was also approved in the European Union.

For your information, the attached is the text of press release made by the company on March 26 (ET/US). Please, however, note that the statement in the document does not apply to the facts and perspectives taking place in Japan.

In Japan Banyu Pharmaceutical Co., Ltd. and Ono Pharmaceutical Co., Ltd. are jointly conducting Phase III clinical studies for the drug based on the License Agreement entered between Merck & Co, Inc., Whitehouse Station, N.J., USA and Ono in November 2004 (Development Code: MK-0431 / ONO-5435).

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## **JANUVIA<sup>®</sup> Approved in the European Union for the Treatment of Type 2 Diabetes**

### **Once-Daily JANUVIA Provides Powerful Glucose Lowering and Is the First DPP-4 Inhibitor To Be Adopted by the European Commission**

WHITEHOUSE STATION, N.J., U.S.A., 26 MARCH, 2007 – JANUVIA<sup>®</sup> (sitagliptin<sup>1</sup>), Merck Sharp & Dohme's (MSD's) treatment for patients with type 2 diabetes, has been granted a license from the European Commission. JANUVIA is the first and only prescription medication in a new class of drugs known as dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors), which enhance the body's own ability to lower blood sugar when it is elevated.

JANUVIA has been adopted in the European Union (EU) for the treatment of type 2 diabetes mellitus to improve glycaemic control in combination with metformin when diet and exercise plus metformin do not provide adequate glycaemic control. For patients with type 2 diabetes mellitus in whom use of a PPAR $\gamma$  agonist (i.e. a thiazolidinedione) is appropriate, JANUVIA is indicated in combination with the PPAR $\gamma$  agonist when diet and exercise plus the PPAR $\gamma$  agonist alone do not provide adequate glycaemic control.

#### **Once-daily JANUVIA provides powerful glucose-lowering**

In a non-inferiority trial, the efficacy of JANUVIA was comparable to a commonly used glucose-lowering agent (glipizide). JANUVIA was compared to glipizide in patients already on metformin with a mean HbA<sub>1c</sub> baseline of 7.5 percent. Both JANUVIA and glipizide lowered HbA<sub>1c</sub> by 0.7 percent. In addition, the group treated with JANUVIA had weight loss of 1.5 kg compared to weight gain of 1.1 kg with glipizide. Hypoglycaemia (when blood sugar becomes too low) was also significantly more common in patients treated with glipizide plus metformin (32 percent) compared to patients treated with JANUVIA plus metformin (4.9 percent).

In another add-on to metformin study, more than three times as many patients uncontrolled on metformin reached the International Diabetes Federation HbA1c<sup>2</sup> goal of <6.5% when JANUVIA was added compared to those who continued on metformin alone. JANUVIA has been shown to demonstrate complementary glucose efficacy when added to metformin or a thiazolidinedione (TZD).

In the placebo-controlled phase III clinical trials, the incidence of hypoglycaemia in patients taking JANUVIA was comparable to patients taking placebo (1.2 percent, JANUVIA vs. 0.9 percent, placebo). In a pooled analysis of patients participating in 9 clinical trials of up to 2 years in duration, discontinuation due to adverse experiences considered drug-related was 0.8 percent with JANUVIA and 1.5 percent with other treatments. In this pooled analysis, no adverse reactions considered as drug-related were reported in patients treated with JANUVIA occurring in excess (> 0.2 percent and difference > 1 patient) of that in patients treated with a comparative treatment. Drug-related adverse experiences that were reported in individual studies are provided in the product label.

In addition to the drug-related adverse experiences referenced above, adverse experiences reported regardless of causal relationship to medication and occurring in at least 5% and more commonly in patients treated with JANUVIA included; upper respiratory tract infection and nasopharyngitis. Low overall incidence of adverse events reported regardless of causality also included nausea, somnolence, upper abdominal pain, diarrhoea, hypoglycaemia, osteoarthritis, and pain in extremity.

The approval applies to all of the 27 countries that are members of the EU, including the United Kingdom, Germany, France, Italy and Spain, as well as in Norway and Iceland (who follow the EMEA decisions). JANUVIA will be launched shortly in the EU countries. JANUVIA is now approved for use in 42 countries around the world including Mexico, the United States, and the Philippines.

"Currently in Europe more than 53 million people, or 8 percent of the population, live with diabetes. Of these, nearly half are not at their glucose goals. The approval of JANUVIA in the EU provides patients with a much-needed treatment option to help combat this disease, and underscores MSD's commitment to the field of diabetes," said Stefan Oschmann, president, Europe, Middle East, Africa and Canada, Merck & Co., Inc.

The European Commission adoption follows a review of comprehensive data supporting the efficacy, safety and tolerability profile of JANUVIA. The submission package consisted of

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<sup>1</sup> Sitagliptin is also known as XELEVIA, which has been filed as a duplicate marketing authorization with a different brand name for use in the case of co-marketing in certain EU countries.

<sup>2</sup> HbA1c is a measure of a person's average blood glucose over a two- to three-month period.

studies involving more than 3,600 patients with type 2 diabetes receiving treatment with sitagliptin at a dose of 100 mg/day or more.

### **About JANUVIA**

JANUVIA is an oral, once daily potent and highly selective DPP-4 inhibitor. DPP-4 inhibitors work by enhancing a natural body process that lowers blood sugar, the incretin system. When blood sugar is elevated, incretins work in two ways to help the body regulate high blood sugar levels: they trigger the pancreas to increase the release of insulin and signal the liver to reduce its production of glucose. DPP-4 inhibitors enhance the body's own ability to control blood sugar levels by increasing the active levels of these incretin hormones in the body, helping to decrease blood sugar levels in patients with type 2 diabetes. JANUVIA is currently approved in at least one country in the major regions around the world including Asia Pacific, Europe, the United States and Latin America.

### **Expanding clinical trial program for JANUVIA**

Merck's clinical development program for sitagliptin is robust and continues to expand with 47 studies completed or under way, and nine more studies set to begin this year. There are more than 7,600 patients in the Company's clinical studies with about 4,700 of these patients being treated with sitagliptin. Additionally, about 1,900 patients have been treated with sitagliptin for more than a year.

### **About Merck & Co., Inc.**

Merck & Co., Inc. which operates as Merck, Sharp & Dohme (MSD) in countries outside the U.S., is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.com).

### **Forward-looking statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include

statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. MSD undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect MSD's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of MSD's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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