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Results of Phase III Studies of Sitagliptin, new oral treatment of diabetes, were presented by Merck & Co., Inc. at ADA

Merck & Co., Inc, (Whitehouse Station, New Jersey, USA) released Phase III data for sitagliptin (MK-0431/ONO-5435), the company's new oral medicine for type 2 diabetes, at the American Diabetes Association (ADA) 66th Scientific Sessions which is being held in Washington D.C. now. Attached for your information is the press release Merck issued on the Phase III data of sitagliptin presented at ADA.

In Japan, sitagliptin is in Phase II by Banyu Pharmaceutical Co., Ltd. In accordance with the licensing agreement between Merck and Ono Pharmaceutical Co., Ltd., the product will be co-developed by Banyu and Ono from Phase III studies.

This sitagliptin agreement is one among other licensing agreements between Ono and Merck, namely on Proglia®/ONO-2506 injection (acute cerebral infarction) and apprepitant (MK-0869/ONO-7436, chemotherapy-induced nausea and vomiting).

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For your information, the attached press release covers the data presented on the first day of ADA (June 10 EST). There will be another press release to cover the data which will be presented at the Late-Breaker Oral Presentation on the final day of ADA (June 13 EST). This press release will be distributed in Japan on June 14 (Japan time).

Newly Released Phase III Studies for JANUVIA™, Merck Sharp & Dohme's Investigational Once-Daily Medicine for Type 2 Diabetes, Showed Significantly Reduced Blood Sugar Levels When Used as Monotherapy or as Add-On Treatment

WASHINGTON, D.C., June 10, 2006 – Newly released Phase III studies presented here today at the American Diabetes Association (ADA) 66th Annual Scientific Sessions demonstrated that JANUVIA™ (sitagliptin), Merck Sharp and Dohme's (MSD) investigational oral, once-daily medicine for type 2 diabetes, significantly reduced blood sugar (glucose) levels when used as monotherapy or as an add-on treatment to two commonly used therapies (metformin or pioglitazone). Additionally, treatment with JANUVIA improved measures of beta cell function. Beta cells are cells in the pancreas that make and release insulin (a hormone that helps the body use glucose for energy).

In these studies, JANUVIA had an overall incidence of side effects comparable to placebo and was generally well tolerated. The most common side effects reported with JANUVIA (≥3% and higher than placebo) were stuffy or runny nose and sore throat; headache; diarrhea; upper respiratory infection; joint pain; and urinary tract infection (with differences ranging from 0.1% to 1.5% vs. placebo).

JANUVIA is an investigational once-daily medicine that would potentially be the first in a new class of oral drugs (dipeptidyl peptidase-4 [DPP-4] inhibitors) that enhances the body's own ability to lower blood sugar (glucose) when it is elevated. The mechanism of action of DPP-4 inhibitors is distinct from that of any currently available class of glucose lowering agents.

An important predictive factor of the magnitude of HbA1C reduction in response to anti-hyperglycemic therapy is a patient's HbA1C level at baseline; HbA1C is a measure of a person's average blood glucose over a two- to three-month period. In three monotherapy studies in patients with mildly to moderately elevated HbA1C levels (mean baseline HbA1C levels ranged from 7.5% to 8.1%), JANUVIA 100 mg once daily (the proposed registration dose) showed significant mean placebo-subtracted reductions in HbA1C ranging from 0.60% to 1.05%.

In these studies, the mean effect of JANUVIA on HbA1C levels was greater with higher baseline HbA1C levels. JANUVIA demonstrated significant mean placebo-subtracted HbA1C reductions that ranged from 1.20% to 1.50% in patients with higher baseline HbA1C levels (a pre-defined stratum of patients with baseline HbA1C ≥9%; patients enrolled in the studies had a baseline HbA1C ≥6.5% and ≤10%). In patients in the lowest pre-defined stratum (baseline HbA1C <8%), the mean placebo-subtracted HbA1C reductions ranged from 0.44% to 0.57%. The monotherapy studies also showed JANUVIA substantially reduced both fasting plasma glucose (FPG) and postprandial, or post-meal, glucose (PPG) levels.

“The data for JANUVIA presented today showed significant glucose-lowering effects across a range of patients with type 2 diabetes, especially in those with more elevated baseline HbA1C levels. In these studies, a low rate of hypoglycemia was observed and JANUVIA was generally weight neutral," said Dr. Edward S. Horton, vice president of the Joslin Diabetes Center in Boston and head of its clinical research division. “If approved, JANUVIA would provide a new and valuable addition to the available treatments for physicians to treat this complex and chronic disease.”

In two Phase III add-on studies in patients whose blood glucose levels were inadequately controlled on either metformin or a TZD (pioglitazone) with mildly to moderately elevated baseline HbA1C levels (mean baseline HbA1C approximately 8%), JANUVIA 100 mg once daily showed significant additional mean placebo-subtracted HbA1C reductions of 0.65% and 0.70% respectively (both $p<0.001$ vs. placebo). Approximately twice as many patients achieved goal HbA1C of less than 7% with the addition of JANUVIA vs. placebo (47 percent vs. 18 percent and 45 percent vs. 23 percent in the metformin add-on study and pioglitazone add-on study, respectively).

Beta cell dysfunction, characterized by a decreased ability to produce adequate levels of insulin, occurs early in the disease process and is required for the development of type 2 diabetes. In the monotherapy studies, JANUVIA produced significant improvements in measures of beta cell function: HOMA-Beta and the fasting proinsulin/insulin ratio.

"Merck is committed to discovering and developing novel treatments for patients with type 2 diabetes. We believe that our investigational medicine JANUVIA represents an example of this commitment." said John Amatruda, M.D., vice president of clinical research, Metabolic Disorders, Merck & Co., Inc. "Merck has a substantial research program for JANUVIA and we look forward to sharing the results of pre-clinical, mechanism-of-action, and clinical studies with the scientific community."

The safety and tolerability of JANUVIA at once-daily doses of 100 mg and 200 mg (twice the proposed registration dose) were assessed by pooling data from two monotherapy and two add-on studies. The overall incidence of clinical and laboratory adverse experiences was similar between JANUVIA and placebo. The incidence of hypoglycemia was similar between JANUVIA and placebo (1.2% in 100 mg, 0.9% in 200 mg, and 0.9% in placebo) and no clinically meaningful changes compared to placebo were observed in body weight with JANUVIA in these studies. The most common side effects (≥3% and greater than placebo) reported with JANUVIA were stuffy or runny nose and sore throat; headache; diarrhea; upper respiratory infection; joint pain; and urinary tract infection (with differences ranging from 0.1% to 1.5% vs. placebo).

For laboratory assessments, no clinically meaningful differences in the occurrence of pre-defined changes in laboratory values were noted. Although not clinically meaningful, small increases in uric acid, in white cell blood count (due to a small increase in neutrophil count), and a small decrease in alkaline phosphatase were observed with JANUVIA compared with placebo. In these studies, no significant changes in vital signs or in ECG including in QTc intervals were observed.

Study Results Presented for JANUVIA as Monotherapy

In the monotherapy studies, JANUVIA 100 mg once daily was shown to significantly reduce HbA1C and FPG in a 12-week study in Japanese patients (Study #201), and to significantly lower HbA1C, FPG and PPG levels in 24-week (Study #021) and 18-week (Study #023) studies.

POSTER #537-P (Study #201)

This randomized, double-blind, placebo-controlled, parallel group study evaluated the efficacy and tolerability of JANUVIA in 151 Japanese patients, ages 27 to 69 years, with type 2 diabetes. In this study, patients with type 2 diabetes entered an eight-week diet and exercise run-in period. After the run-in period, patients with HbA1C between 6.5% and 10% were eligible to be randomized to JANUVIA 100 mg once daily or placebo for a 12-week treatment period. Patients were randomized 1:1 to JANUVIA (n=75) or placebo (n=76).

The mean baseline HbA1C was 7.5% in the JANUVIA group and 7.7% in the placebo group. At week 12, HbA1C decreased by -0.65% in the JANUVIA group compared with an increase of 0.41% in the placebo group, for a between-treatment group difference in HbA1C of -1.05% (95% CI: -1.27, -0.84%; $p<0.001$). In this study, JANUVIA 100 mg once daily showed significant mean reductions in the following measures:

Measurement	Value (placebo-subtracted)
HbA1C	-1.05% (p<0.001)
FPG	-31.9 mg/dL (p<0.001)
2-hour PPG	-80.9 mg/dL (p<0.001)

In this monotherapy study in Japanese patients, the overall incidence of adverse experiences reported was similar between treatment groups. Treatment with JANUVIA 100 mg was well tolerated with no reported adverse experiences of hypoglycemia. Body weight decreased from baseline by -0.1 kg with the proposed registration dose of JANUVIA 100 mg and by -0.7 kg in patients on placebo (p=0.003, difference between treatment groups).

ABSTRACT #1995-PO (Study #021)

The efficacy and safety of JANUVIA were assessed in a 24-week, randomized, double-blind, placebo-controlled Phase III study of 741 patients with primarily mild to moderate type 2 diabetes (mean baseline HbA1C 8%). After a drug washout period for those on an anti-hyperglycemic agent and a 2-week single-blind placebo run-in period, the patients, ages 18 to 75 years, with an HbA1C between 7% and 10% were randomized (1:1:1) to placebo, JANUVIA 100 mg once-daily, or JANUVIA 200 mg once daily. At the proposed registration dose of 100 mg, JANUVIA produced significant mean glucose-lowering results:

Measurement	**Value (placebo-subtracted)**	
HbA1C	-0.79%	(p<0.001)
FPG	-17.1 mg/dL	(p<0.001)
2-hour PPG	-46.7 mg/dL	(p<0.001)

In a pre-specified stratification of patients based on their baseline HbA1C, patients with a higher baseline HbA1C experienced greater mean reductions of HbA1C than those with lower baseline levels. The following table provides the range of responses seen with JANUVIA 100 mg in patients with different baseline HbA1C values:

Baseline HbA1C	**Reduction (placebo-subtracted)**	
≥9 (mean 9.58%)	-1.52%	(p<0.001)
8 to 8.9% (mean 8.36%)	-0.80%	(p<0.001)
<8% (mean 7.39%)	-0.57%	(p<0.001)

In this 24-week monotherapy study, the rate of hypoglycemia or gastrointestinal adverse experiences was similar between JANUVIA and placebo. Body weight decreased from baseline by -0.2 kg with the proposed registration dose of JANUVIA 100 mg and by -1.1 kg in patients on placebo (p=0.008, difference between treatment groups).

ABSTRACT #1996-PO (Study #023)

The efficacy and safety of JANUVIA were assessed in a randomized, double-blind, placebo-controlled, 18-week study in patients, ages 27 to 76 years, with type 2 diabetes. After a drug washout period for those on an anti-hyperglycemic agent and a two-week, single-blind, placebo run-in period, the 521 patients with HbA1C between 7% and 10% were randomized in a 1:2:2 ratio to placebo, JANUVIA 100 mg once daily or JANUVIA 200 mg once daily. In this study, JANUVIA 100 mg once daily produced significant mean reductions in HbA1C, FPG, and PPG in

the patients with primarily mild to moderate type 2 diabetes (mean baseline HbA1C 8.1%). The mean reductions observed were:

Measurement	Value (placebo-subtracted)	
HbA1C	-0.60%	(p<0.001)
FPG	-19.7 mg/dL	(p<0.001)
2-hour PPG	-46.3 mg/dL	(p<0.05)

When stratified according to their baseline HbA1C values, patients demonstrated the following range of response for mean reduction of HbA1C:

Baseline HbA1C	Reduction (placebo-subtracted)	
≥9 (mean 9.48%)	-1.20%	(p<0.001)
8 to 8.9% (mean 8.40%)	-0.61%	(p=0.004)
<8% (mean 7.37%)	-0.44%	(p=0.003)

In this 18-week monotherapy study, there was no significant increase in hypoglycemia or gastrointestinal adverse events with JANUVIA compared to placebo. Body weight was similarly reduced with JANUVIA 100 mg (-0.6 kg) and placebo (-0.7 kg).

Study Results Presented for JANUVIA as Add-On Therapy

In two separate 24-week, Phase III add-on studies, JANUVIA 100 mg once daily significantly improved HbA1C levels when added to therapy for patients inadequately controlled on metformin or a pioglitazone (a TZD) alone. In this study, patients had mildly to moderately elevated HbA1C levels (mean baseline HbA1C of approximately 8%).

ABSTRACT #501-P (Study #020)

In a 24-week, double-blind study, 701 patients who had inadequate glycemic control with metformin (at least 1500 mg daily) were randomized to add either JANUVIA 100 mg once daily or placebo. JANUVIA 100 mg once daily added to patients inadequately controlled on metformin and with mildly to moderately elevated HbA1C levels (mean baseline HbA1C 8.0%) led to a significant additional mean reduction in HbA1C, FPG, and PPG at 24 weeks, as shown:

Measurement	Value (placebo-subtracted)	
HbA1C	-0.65%	(p<0.001)
FPG	-25.4 mg/dL	(p<0.001)
2 hour PPG	-50.6 mg/dL	(p<0.001)

When added to patients inadequately controlled on metformin, JANUVIA was generally well tolerated, with no increased incidence of hypoglycemia or gastrointestinal adverse events compared with the placebo arm of the study. Body weight was similarly reduced with the treatment group with JANUVIA 100 mg + metformin and placebo + metformin.

ABSTRACT #556-P (Study #019)

In another 24-week, double-blind study, 353 patients who had not achieved glycemic control with pioglitazone 30 mg or 45 mg daily were randomized to receive pioglitazone with JANUVIA 100 mg once daily or pioglitazone with placebo. The patients had mildly to moderately elevated HbA1C levels (mean baseline HbA1C 8.05%). JANUVIA 100 mg once daily added to pioglitazone resulted in significant additional reductions in HbA1C and FPG when compared to pioglitazone with placebo, as shown:

Measurement	**Value (placebo-subtracted)**
HbA1C	-0.70% (p<0.001)
FPG	-17.7 mg/dL (p<0.001)

JANUVIA 100 mg in combination with pioglitazone was generally well tolerated with an overall incidence of adverse events and hypoglycemia similar to the placebo plus pioglitazone combination. A slightly higher incidence of abdominal pain, and of the overall incidence of pre-specified, selected gastrointestinal adverse experiences, was observed with patients receiving JANUVIA. Body weight changes were similar between the treatment group of JANUVIA 100 mg + pioglitazone and placebo + pioglitazone.

Study Results Presented for Dose Adjustment in Patients with Renal Impairment

JANUVIA is predominantly eliminated by the kidney. Because of this, lower doses were studied for patients with moderate and severe renal insufficiency in order to achieve plasma concentrations of JANUVIA in patients with renal impairment similar to those in patients with normal renal function. Merck conducted a dose adjustment study in such patients including patients with end-stage renal disease on dialysis.

In this 54-week, placebo-controlled study of type 2 patients (N=91) with renal impairment, JANUVIA was administered at 25 mg to patients with severe renal impairment including patients on dialysis and 50 mg to patients with moderate renal impairment. In this study, there were 2.5 times more patients on JANUVIA (n=65) than placebo (n=26), and 4.5 times more patients on JANUVIA than placebo had pre-existing coronary artery disease or heart failure.

The efficacy with adjusted doses of JANUVIA was similar to other clinical studies with JANUVIA. After all patients completed at least 38 weeks of treatment, the rate of overall adverse experiences (AEs), serious AEs and discontinuations due to AEs along with laboratory AEs and cardiac AEs was similar between the two study groups. There were four deaths in 65 patients receiving JANUVIA and one death in 26 patients who received placebo. In patients receiving JANUVIA, one patient died due to pancreatic cancer and three patients on dialysis with pre-existing cardiovascular disease died (sudden death, myocardial infarction and during hemodialysis). One of the 26 patients receiving glipizide died from sepsis. None of the deaths was characterized by investigators as drug-related.

This study continues as planned with final results of the 54-week treatment period expected in the fall of 2006.

Late-Breaker Oral Presentation

JANUVIA will be highlighted in a late-breaking presentation at the annual ADA meeting on Tuesday, June 13, 2006.

International Press Briefing

MSD will present Phase III data on JANUVIA to media based outside of the US at a press briefing at the Ronald Reagan Building and International Trade Center, Washington DC, USA on Monday 12th June at 19.00 EST.

About JANUVIA

JANUVIA is Merck Sharp & Dohme's investigational oral, once daily DPP-4 inhibitor for the treatment of type 2 diabetes. JANUVIA is a potent and highly selective DPP-4 inhibitor. DPP-4 inhibitors work by enhancing a natural body system 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 insulin and signal the liver to reduce glucose production. 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 has been accepted for standard review by the U.S. Food and Drug Administration (FDA). Merck expects FDA action on the NDA by mid-October. The Company also is moving forward with filings in countries outside the United States. The filing of the New Drug Application to the FDA for MK-0431A, the Company's investigational oral medicine combining

JANUVIA with metformin for type 2 diabetes, will occur in 2006 vs. in 2007 as initially anticipated.

About Type 2 Diabetes

Type 2 diabetes is a condition in which the body has elevated blood sugar or glucose. With type 2 diabetes, the body may not make enough insulin (which helps the body use glucose), the insulin that the body produces may not work as well as it should, or the body may make too much glucose. Patients with diabetes can develop heart disease, kidney disease, blindness, vascular or neurological problems that can lead to amputation and they can suffer increased mortality.

Nearly 21 million people in the United States, or seven percent of the population, have diabetes, with type 2 diabetes accounting for 90 to 95 percent of the cases. Approximately two-thirds of people diagnosed with type 2 diabetes have not achieved adequate control of their blood sugar levels (HbA1C less than seven percent as recommended by the American Diabetes Association). It is estimated that one in three Americans born in 2000 will develop diabetes sometime during their lifetime. There are currently more than 194 million people with diabetes worldwide, and if nothing is done to slow the epidemic, the number may exceed to 333 million by 2025.

About Merck

Merck & Co., Inc., which operates in many countries as Merck Sharp & Dohme (MSD), is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in more than 20 therapeutic categories. 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

Forwarding-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. Merck 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 Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2005, and in its periodic reports on Form 10-Q and Form 8-K, which the company incorporates by reference.

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