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Results of Phase III Studies of Sitagliptin, new oral treatment of diabetes, were presented by Merck & Co., Inc. at ADA (The 2nd Announcement)

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.

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For your information, the attached press release covers the data presented at the Late-Breaker Oral Presentation on the final day of ADA (June 13 EST).

In New Data at One Year, JANUVIA™, an Investigational Once-Daily Medicine for Type 2 Diabetes, Demonstrated the Same Glucose-Lowering Effect as Glipizide (a Sulfonylurea) with Significant Differences in Weight Change and Hypoglycemia

In this non-Inferiority study, the reduction in HbA1C was identical between the two groups at 52 weeks; also, patients on JANUVIA had significant weight loss (vs. weight gain on glipizide) and a significantly lower incidence of hypoglycemia vs. glipizide

WASHINGTON, D.C., June 13, 2006 – In a late-breaking oral presentation here today at the American Diabetes Association (ADA) 66th Annual Scientific Sessions, results from a non-inferiority study comparing JANUVIA™ (sitagliptin) to glipizide (a sulfonylurea) showed JANUVIA was non-inferior to glipizide in significantly reducing blood sugar (glucose) levels at 52 weeks when added to the regimen of patients with type 2 diabetes who had inadequate control on metformin monotherapy. The 52-week data presented were the primary time point analysis for this study, which continues for another year (through 104 weeks).

JANUVIA is Merck Sharp and Dohme's investigational once-daily medicine that, if approved, 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.

"In the new data presented today, JANUVIA demonstrated substantial glucose-lowering effects at one year with a magnitude of HbA1C reduction that was the same as that of glipizide. Additionally, JANUVIA demonstrated weight loss and fewer episodes of hypoglycemia vs. glipizide." said Peter Stein, M.D., senior director, clinical research, Merck & Co., Inc. "These are important findings for a potential new treatment for type 2 diabetes."

In the per-protocol primary analysis (n= 793) of this double-blind, randomized study (N=1,172), JANUVIA 100 mg once daily (proposed registration dose) and glipizide up to 20 mg daily (maximum titrated dose) each showed significant mean reductions in HbA1C[1] of 0.67% vs. baseline ($p<0.001$) in patients with mildly to moderately elevated baseline HbA1C levels (mean 7.5%; enrollment criteria for HbA1C were ≥6.5% and ≤10%). At 52 weeks, JANUVIA achieved the pre-specified bounds for non-inferiority vs. glipizide, and similar proportions of patients achieved HbA1C goal (<7%) in each group (63 percent for JANUVIA vs. 59 percent for glipizide).

In the 52-week data, JANUVIA was generally well tolerated. No significant safety concerns for JANUVIA were apparent based on review of overall incidence of adverse experiences (AEs),

[1] HbA1C is a measure of a person's blood average blood glucose over a two- to three-month period.

incidence of hypoglycemia or gastrointestinal AEs, mean changes and predefined limits of change in laboratory safety parameters and ECG data and vital signs.

Patients in the group treated with JANUVIA 100 mg once daily experienced significant weight loss (mean -1.5 kg) from baseline at 52 weeks, while patients treated with glipizide experienced significant weight gain (mean +1.1 kg) from baseline. The between-treatment difference was statistically significant ($p<0.001$, JANUVIA vs. glipizide). Additionally, patients treated with glipizide experienced a significantly higher rate of hypoglycemia (when blood sugar is too low) vs. JANUVIA (patients experiencing at least one hypoglycemic episode regardless of severity: 32.0% vs. 4.9%, respectively; $p< 0.001$).

Safety and Tolerability across the Clinical Program

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.

HbA1C Goal Attainment across the Clinical Program for JANUVIA

As previously stated, similar proportions of patients taking JANUVIA 100 mg vs. glipizide in the new 52-week data of an active-comparison study achieved HbA1C goal (<7%) (63 percent for JANUVIA vs. 59 percent for glipizide). Additionally, JANUVIA showed significant attainment of HbA1C goal in other key studies reported at the ADA meeting. Differences in percent of patients achieving HbA1C goal (<7%) for patients taking JANUVIA 100 mg as monotherapy vs. placebo were statistically significant ($p<0.001$) in a 24-week study (41 percent vs. 17 percent) and in a 12-week study in Japanese patients (58.1 percent vs. 14.5 percent). Differences in percent of patients achieving HbA1C goal (<7%) for patients taking JANUVIA 100 mg in

combination with metformin (47 percent vs. 18 percent) and with pioglitazone (45 percent vs. 23 percent) were statistically significant ($p<0.001$) in two 24-week studies.

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. The mechanism of action is distinct from any existing class of glucose lowering agents.

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 as planned with filings in countries outside the United States. Also, Merck anticipates that MK-0431A, the investigational medicine combining JANUVIA with metformin for type 2 diabetes, will now be filed in 2006 vs. 2007.

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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