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FDA Approves Once-Daily JANUVIA™, the First and Only DPP-4 Inhibitor Available in the United States for Type 2 Diabetes

WHITEHOUSE STATION, N.J., Oct. 17, 2006 -- Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) approved JANUVIA™ (sitagliptin phosphate), the first and only DPP-4 inhibitor available in the United States for the treatment of type 2 diabetes. JANUVIA has been approved as monotherapy and as add-on therapy to either of two other types of oral diabetes medications, metformin or thiazolidinediones (TZDs), to improve blood sugar (glucose) control in patients with type 2 diabetes when diet and exercise is not enough. The recommended dose of JANUVIA is 100 mg once daily. JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

JANUVIA enhances a natural body system to significantly lower elevated blood sugar

JANUVIA belongs to a new breakthrough class of prescription medications called dipeptidyl peptidase-4 (DPP-4) inhibitors that improves blood sugar control in patients with type 2 diabetes. JANUVIA enhances a natural body system called the incretin system, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas. Through DPP-4 inhibition, JANUVIA works only when blood sugar is elevated to address diminished insulin due to beta-cell dysfunction and uncontrolled production of glucose by the liver due to alpha-cell and beta-cell dysfunction.

"Those patients who are unable to adequately manage their type 2 diabetes with lifestyle changes, like healthy eating and increased physical exercise, and who require medications now have a new product to help regulate their blood sugar levels," said Edward S. Horton, M.D., director of clinical research, Joslin Diabetes Center and professor of medicine, Harvard Medical School, Boston.

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"JANUVIA underscores Merck's commitment to the field of diabetes, and the benefits we strive to bring to patients and physicians who struggle in the treatment of type 2 diabetes," said Richard T. Clark, president and chief executive officer, Merck. "The approval of JANUVIA is a clear example of Merck's focus on developing innovative therapies to improve human health around the world."

JANUVIA had an overall incidence of side effects comparable to placebo

In clinical trials, JANUVIA demonstrated an overall incidence of side effects comparable to placebo. The most common side effects reported with JANUVIA (≥ 5 percent and higher than placebo) were stuffy or runny nose and sore throat, upper respiratory infection, and headache.

JANUVIA provides powerful A1C¹ reductions as monotherapy

In two double-blind, placebo-controlled studies of 24 weeks ($n=473$) and 18 weeks ($n=296$) in patients with mild to moderate baseline A1C levels (mean 8.0%; enrollment range 7.0% to 10.0%), JANUVIA 100 mg once-daily showed significant mean differences in A1C from placebo of -0.8% and -0.6%, respectively ($p<0.001$). As is typical in trials of agents to treat type 2 diabetes, mean response to JANUVIA in A1C lowering appears to be related to the degree of A1C elevation at baseline. In a pooled analysis of these two monotherapy studies, a pre-specified subgroup analysis showed that when patients were grouped by baseline A1C into those with mildly elevated A1C levels ($<8\%$, $n=411$), moderately elevated A1C levels ($\geq 8\%$ to $<9\%$, $n=239$) and the highest elevated A1C levels ($\geq 9\%$, $n=119$), mean differences in A1C from placebo after 18 weeks were -0.6%, -0.7% and -1.4%, respectively ($p<0.001$ for treatment by subgroup interactions).

JANUVIA has a significant and complementary effect when added to metformin or TZDs

JANUVIA addresses two of the three key defects that cause poor glucose control: diminished insulin release due to beta-cell dysfunction and uncontrolled production of glucose by the liver due to alpha-cell and beta-cell dysfunction. By adding JANUVIA to the insulin sensitizers metformin or pioglitazone (a TZD), the three key defects of type 2 diabetes can be addressed: insulin resistance, beta-cell dysfunction (decreased insulin release), and alpha-cell dysfunction (unsuppressed hepatic glucose production).

In separate 24-week studies of patients with type 2 diabetes who were inadequately controlled on either metformin or pioglitazone alone, JANUVIA 100 mg once daily provided a complementary effect. JANUVIA showed significant mean differences in A1C from placebo of -0.7% in the metformin add-on study ($p<0.001$) and -0.7% in the pioglitazone add-on study

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¹ A1C is a measure of a person's average blood glucose over a two- to three-month period.

($p < 0.001$). In those same studies, the mean A1C reduction from baseline with JANUVIA was 0.7% from a mean baseline A1C of 8.0% and 0.9% from a mean baseline of 8.1%, respectively.

Approximately twice as many patients got to A1C goal of <7% with JANUVIA

In the metformin add-on study, more than twice as many patients uncontrolled on metformin got to A1C goal of <7% when JANUVIA was added (47 percent with JANUVIA and metformin vs. 18 percent for patients continuing on metformin alone) ($p < 0.001$). Similarly, in the pioglitazone add-on study, 45 percent of patients adding JANUVIA to their regimen reached the A1C goal of <7% compared with 23 percent who continued on pioglitazone alone ($p < 0.001$).

JANUVIA provides powerful A1C lowering through combined reductions of both PPG and FPG throughout the day

JANUVIA has been demonstrated to provide a 24-hour glucose response at mealtime, between meals and overnight. In a 24-week, placebo-controlled study of patients uncontrolled on metformin, adding JANUVIA 100 mg once daily substantially reduced PPG (or post-meal glucose) levels by 51 mg/dL and FPG by 25 mg/dL compared to patients continuing on metformin alone ($p < 0.001$).

Treatment with JANUVIA was not associated with weight gain or increased risk of hypoglycemia

JANUVIA once-daily was weight neutral compared to placebo in clinical trials. Mean body weight decreased 0.2 kg (vs. 1.1 kg decrease for placebo) and 0.7 kg (vs. 0.6 kg), respectively, in two 24-week trials: one in patients taking JANUVIA as monotherapy ($n=193$) and one in combination with metformin ($n=399$). The overall incidence of hypoglycemia in patients treated with JANUVIA 100 mg was similar to placebo (1.2 percent vs. 0.9 percent, respectively) across the clinical program. The incidence of selected gastrointestinal adverse reactions in patients treated with JANUVIA was as follows: abdominal pain (JANUVIA, 2.3 percent; placebo, 2.1 percent), nausea (1.4 percent, 0.6 percent), and diarrhea (3.0 percent, 2.3 percent).

Glucose-dependent mechanism of action

The novel mechanism of JANUVIA is glucose-dependent, responding to the presence of elevated glucose and resulting in the release of insulin and decrease of glucagon only when needed, thereby lowering the potential for hypoglycemia. By inhibiting the DPP-4 enzyme, JANUVIA significantly increases the levels of active incretin hormones, increasing the synthesis and release of insulin from the pancreatic beta cells and decreasing the release of glucagon from the pancreatic alpha cells.

Indications and contraindications for JANUVIA

JANUVIA is indicated, as an adjunct to diet and exercise, to improve glycemic control in patients with type 2 diabetes mellitus. JANUVIA is also indicated to improve glycemic control, in combination with metformin or a TZD, in patients with type 2 diabetes when the single agent alone plus diet and exercise do not provide adequate glycemic control. JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. There are no contraindications for JANUVIA.

Selected cautionary information for JANUVIA

Because JANUVIA is renally eliminated, and to achieve plasma concentrations of JANUVIA similar to those in patients with normal renal function, a dosage adjustment is recommended in patients with moderate renal insufficiency and in patients with severe renal insufficiency or with end-stage renal disease (ESRD) requiring hemodialysis or peritoneal dialysis. Safety and effectiveness of JANUVIA in pediatric patients have not been established. There are no adequate and well-controlled studies in pregnant women. JANUVIA should be used during pregnancy only if clearly needed. Caution should be exercised when JANUVIA is administered to a nursing woman.

Dosing of JANUVIA

The recommended dose of JANUVIA is 100 mg once daily, with or without food, for all approved indications. No dosage adjustment is needed for patients with mild to moderate hepatic insufficiency or in patients with mild renal insufficiency ($\text{CrCl} \geq 50 \text{ mL/min}$). To achieve plasma concentrations of JANUVIA similar to those in patients with normal renal function, lower dosages are recommended in patients with moderate and severe renal insufficiency as well as in ESRD patients requiring hemodialysis. For patients with moderate renal insufficiency ($\text{CrCl} \geq 30$ to $< 50 \text{ mL/min}$), the dose of JANUVIA is 50 mg once daily. For those with severe renal insufficiency ($\text{CrCl} < 30 \text{ mL/min}$) or with ESRD requiring dialysis, the dose of JANUVIA is 25 mg once daily. Because there is a need for dosage adjustment based upon renal function, assessment of renal function is recommended prior to initiation of JANUVIA and periodically thereafter.

Pricing and availability of JANUVIA

The price of once-daily JANUVIA will be \$4.86 per tablet. JANUVIA will be broadly available in pharmacies in the near future.

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, the insulin that the body produces may

not work as well as it should, and/or the liver may release too much glucose.

Nearly 21 million people in the United States (7 percent of the population) have diabetes, with type 2 accounting for 90-95 percent of cases. Approximately half of people diagnosed with type 2 diabetes have not achieved adequate control of their blood sugar levels. Patients with diabetes can develop heart disease, kidney disease, blindness, vascular or neurological problems that can lead to amputation and can suffer increased rates of mortality.

It is estimated that one in three Americans born in 2000 will develop diabetes sometime during their lifetime. There are currently more than 230 million people with diabetes worldwide, and if nothing is done to slow the epidemic, the worldwide number may exceed 350 million by 2025. The American Diabetes Association recommends that patients with type 2 diabetes achieve a target A1C level of <7%, while the American Academy of Clinical Endocrinologists recommends a target A1C level of <6.5%.

Expanding clinical development program for JANUVIA

Merck's clinical development program for JANUVIA is robust and continues to expand with 43 studies completed or under way, and four more studies set to begin this year. There are about 6,700 patients in the Company's clinical studies with about 4,700 of these patients being treated with JANUVIA. Additionally, about 1,100 patients have been treated with JANUVIA for more than a year.

JANUVIA also is being investigated as part of a single tablet combination with metformin (MK-0431A). MK-0431A has been accepted for standard review by the FDA, and an FDA action is expected by the end of March 2007. Regulatory filings in countries outside the United States are moving forward as planned.

About Merck

Merck & Co., Inc. 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.

Merck 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. 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.

NOTE: The views stated herein are those of Dr. Edward Horton and do not necessarily represent the views of Joslin Diabetes Center. Joslin Diabetes Center does not endorse products, did not participate in any tests for the product JANUVIA and makes no representations as to its quality or efficacy.

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Prescribing information and patient product information for JANUVIA are attached.