MERCK

News Release

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FDA Approves JANUMET™ for Type 2 Diabetes, Offering Powerful Glucose Control of a DPP-4 Inhibitor and Metformin in a Single Tablet

JANUMET (sitagliptin/metformin HCl) provides significantly greater A1C[1] reduction than metformin alone and helped more than twice as many patients get to A1C goal

WHITEHOUSE STATION, N.J., April 2, 2007 -- Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) approved JANUMET™, the first and only tablet combining a dipeptidyl peptidase-4 (DPP-4) inhibitor, sitagliptin (also known as JANUVIA™), and metformin for the treatment of type 2 diabetes.

JANUMET has been approved, as an adjunct to diet and exercise, to improve blood sugar (glucose) control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin. JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

The FDA approved JANUMET based upon clinical data including sitagliptin plus metformin as separate tablets. A clinical bioequivalence study has demonstrated the equivalence between JANUMET and sitagliptin plus metformin as separate tablets.

"JANUMET is the latest advance in Merck's longstanding commitment to developing effective medicines for type 2 diabetes," said Adam Schechter, president, United States Human Health, Merck & Co., Inc. "With JANUMET and JANUVIA, Merck now has a growing family of products that provides physicians with important treatment options for patients with type 2 diabetes."

JANUMET delivers proven efficacy

A 24-week, randomized, double-blind, placebo-controlled study with 701 patients with mildly to moderately elevated A1C levels (mean baseline 8.0 percent) inadequately controlled

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

on metformin, showed that patients taking JANUMET[2] (n=453) experienced significant additional mean placebo-subtracted reductions in A1C of 0.7 percent beyond that achieved by patients who continued on metformin alone (n=224) ($p<0.001$). In the study, more than twice as many patients on JANUMET (213 of 453 patients, or 47 percent) reached the American Diabetes Association's A1C goal of <7 percent compared with patients on metformin alone (41 of 224 patients, or 18 percent) ($p<0.001$).

JANUMET combines two agents with proven ability to deliver significant improvements in glycemic control: metformin, a commonly used effective glucose-lowering agent, and sitagliptin, a DPP-4 inhibitor that provides significant A1C lowering as monotherapy and as add-on therapy to metformin or thiazolidinediones (TZDs) based on clinical trials. JANUMET, like metformin, is dosed twice daily with meals. Consistent with the labeling for metformin alone, the labeling for JANUMET contains a boxed warning for lactic acidosis, a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with JANUMET.

"Physicians use several different medications in combination to address the multiple defects associated with type 2 diabetes, however, less than half of patients achieve and maintain their goal A1C levels," said Nir Barzilai, M.D., professor of Medicine and Molecular Genetics, director of the Institute for Aging Research, Albert Einstein College of Medicine. "JANUMET is an important new treatment option for many patients who need more than one therapy to control their type 2 diabetes because it addresses all three key defects of type 2 diabetes for improved glycemic control."

Patients treated with JANUMET experienced weight loss comparable to metformin alone, with no increased risk of hypoglycemia, edema, or GI disturbances beyond metformin alone

As clinicians select agents to add to the treatment regimens of patients with uncontrolled type 2 diabetes, it is important to consider issues such as weight gain, hypoglycemia, edema, and gastrointestinal disturbances.

In a 24-week study, mean body weight decreased 1.5 lb (n=399) in patients taking JANUMET, similar to patients taking metformin alone (1.3 lb decrease; n=169). There was no increased risk of hypoglycemia in patients treated with JANUMET (1.3 percent vs. metformin alone, 2.1 percent) and no increased risk of edema in patients treated with JANUMET

[2] Clinical data referenced in this press release for JANUMET were from studies including sitagliptin plus metformin as separate tablets. A clinical bioequivalence study has demonstrated the equivalence between JANUMET and sitagliptin plus metformin as separate tablets.

(0.9 percent vs. metformin alone, 1.3 percent). In addition, there was no significant increase in the risk of overall gastrointestinal adverse reactions in patients treated with JANUMET (11.6 percent vs. metformin alone, 9.7 percent). Specific gastrointestinal adverse reactions included diarrhea (JANUMET, 2.4 percent vs. metformin alone, 2.5 percent), abdominal pain (JANUMET, 2.2 percent vs. metformin alone, 3.8 percent), nausea (JANUMET, 1.3 percent vs. metformin alone, 0.8 percent), and vomiting (JANUMET, 1.1 percent vs. metformin alone, 0.8 percent). The most common adverse experience in sitagliptin monotherapy reported regardless of investigator assessment of causality in ≥5 percent of patients and more commonly than in patients given placebo was nasopharyngitis.

Clinicians should be mindful that hypoglycemia could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as sulfonylureas and insulin) or ethanol. Elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects.

By incorporating the novel mechanism of DPP-4 inhibition, JANUMET uniquely addresses the three key defects of type 2 diabetes

With the two active components, sitagliptin and metformin, JANUMET has a comprehensive mechanism of action that targets all three key defects of type 2 diabetes for improved glycemic control: diminished insulin release, uncontrolled production of glucose, and insulin resistance.

The sitagliptin component in JANUMET address 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 inhibiting the DPP-4 enzyme, sitagliptin 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.

JANUMET also contains metformin, which addresses the other key defect: insulin resistance. Metformin improves insulin sensitivity by increasing uptake and utilization of glucose by the muscles and tissues of the body. Metformin also decreases hepatic glucose production in a manner that is complementary to sitagliptin.

JANUMET provides powerful A1C lowering through combined reductions of both post-prandial glucose and fasting plasma glucose

JANUMET has been demonstrated to provide 24-hour glucose response - at mealtimes, between meals and overnight. In a 24-week, placebo-controlled study of patients with

inadequate glycemic control on metformin alone, JANUMET significantly reduced post prandial, or post-meal, glucose (PPG) levels beyond metformin alone by a mean of 51 mg/dL in patients with a mean baseline 2-hour PPG of 275 mg/dL (n=387, p<0.001) and fasting plasma glucose levels (FPG) beyond metformin alone by a mean of 25 mg/dL in patients with a mean baseline FPG of 170 mg/dL (n=454, p<0.001).

Indications and contraindications for JANUMET

JANUMET is indicated, as an adjunct to diet and exercise, to improve glycemic control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. Consistent with the labeling for metformin alone, JANUMET is contraindicated in patients with renal disease, renal dysfunction, or abnormal creatinine clearance; and acute or chronic metabolic acidosis, including diabetic ketoacidosis. JANUMET should not be used in patients with type 1 diabetes.

Flexible dosing of JANUMET

JANUMET should be given twice daily with meals, with gradual dose escalation as needed to reduce the gastrointestinal (GI) side effects due to metformin. In this formulation, the dose of sitagliptin remains constant (100 mg daily) and is combined with the two most widely prescribed doses of metformin (1000 mg daily or 2000 mg daily). The recommended starting dose of JANUMET for patients not on prior metformin therapy and for those not adequately controlled on sitagliptin is 50 mg sitagliptin and 500 mg metformin twice-daily with meals. For patients already receiving metformin therapy, the starting dose should be based on the patient's current metformin regimen. The total daily dose should not exceed 100 mg sitagliptin and 2000 mg metformin.

Metformin and sitagliptin are known to be substantially excreted by the kidney. The risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive JANUMET. In the elderly, JANUMET should be carefully titrated to establish the minimum dose for adequate glycemic effect, because aging can be associated with reduced renal function. Any dose adjustment should be based on a careful assessment of renal function. Before initiation of therapy with JANUMET and at least annually thereafter, renal function should be assessed and verified as normal.

Pricing and availability of JANUMET

The price of twice-daily JANUMET will be $4.86 per day. JANUMET will be broadly available in pharmacies in the near future.

Selected cautionary information for JANUMET

JANUMET should be avoided in patients with evidence of hepatic disease. Before initiation of therapy with JANUMET and at least annually thereafter, renal function should be assessed and verified as normal. Patients should be warned against excessive alcohol intake while receiving JANUMET. Patients may require discontinuation of JANUMET and temporary use of insulin during periods of stress and decreased intake of fluids and food such as may occur with fever, trauma, infection or surgery. Patients previously controlled on JANUMET who develop laboratory abnormalities or clinical illness should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. The reported incidence of lactic acidosis in patients receiving metformin hydrochloride is very low (approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years). When lactic acidosis occurs, it is fatal in approximately 50 percent of cases.

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. JANUMET and JANUVIA are not approved to treat the serious problems that may result from high blood sugar.

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 percent, while the American Association of Clinical Endocrinologists recommends a target A1C level of <6.5 percent.

Expanding clinical development program for sitagliptin family

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

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 risk factors and cautionary statements in Item 1A of Merck'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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Prescribing information and patient product information for JANUMET are attached.