NEWS RELEASE

FDA Approves JANUMET® XR (sitagliptin and metformin HCl extended-release) for Type 2 Diabetes, Offering the Powerful Efficacy of JANUMET® (sitagliptin/metformin HCl) Now Available with Once-Daily Convenience

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JANUMET XR can help many patients reach blood sugar goals

Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) approved JANUMET® XR (sitagliptin and metformin hydrochloride (HCl) extended-release) tablets, a new treatment for type 2 diabetes that combines sitagliptin, which is the active component of JANUVIA® (sitagliptin), with extended-release metformin. JANUMET XR provides a convenient once-daily treatment option for healthcare providers and patients who need help to control their blood sugar.

JANUMET XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and extended-release metformin is appropriate. JANUMET XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET XR.

The FDA approved JANUMET XR based upon a clinical bioequivalence study that demonstrated that administration of JANUMET XR was equivalent to co-administration of corresponding doses of the two individual medications, sitagliptin and metformin HCl extended- release. Extended-release metformin was as effective as immediate-

release metformin.

“JANUMET XR is a new treatment that adds once-daily convenience to the powerful efficacy of JANUMET for patients with type 2 diabetes,” said Barry J. Goldstein, M.D., Ph.D., vice president, Diabetes and Endocrinology, Merck. “This is important because many patients with type 2 diabetes require treatment with multiple drugs to maintain blood sugar control, and JANUMET XR is a new option to help more patients get to their glucose goals.”

The labeling for JANUMET XR contains a boxed warning for lactic acidosis, a rare, but serious complication that can occur due to metformin accumulation.

JANUMET XR is contraindicated in patients with renal impairment (e.g., serum creatinine levels ≥1.5 mg/dL for men, ≥1.4 mg/dL for women or abnormal creatinine clearance), which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia; hypersensitivity to metformin HCl; acute or chronic metabolic acidosis, including diabetic ketoacidosis (diabetic ketoacidosis should be treated with insulin); history of a serious hypersensitivity reaction to JANUMET XR or sitagliptin, such as anaphylaxis or angioedema.

When sitagliptin was used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, the incidence of hypoglycemia was increased over that of placebo used in combination with a sulfonylurea or with insulin. Therefore, patients also receiving an insulin secretagogue (e.g., sulfonylurea) or insulin may require a lower dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

There have been postmarketing reports of worsening renal function in patients taking sitagliptin with or without metformin, including acute renal failure, sometimes requiring dialysis. Before initiation of therapy with JANUMET XR and at least annually thereafter, renal function should be assessed and verified as normal. There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, in patients taking sitagliptin with or without metformin. After initiation of JANUMET XR, patients should be observed carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, JANUMET XR should promptly be discontinued and appropriate management should be initiated. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET XR.

The combination of sitagliptin and metformin1 provided greater A1C goal attainment compared to sitagliptin or metformin alone

In a randomized, double-blind, placebo-controlled factorial study in 1,091 patients with type 2 diabetes who had inadequate glycemic control on diet and exercise, the co-administration of metformin immediate-release and sitagliptin twice-daily resulted in a reduction of A1C relative to placebo at 24 weeks. Mean placebo adjusted

reduction was 2.1 percent with initial therapy combining sitagliptin 100 mg daily and metformin immediate-release 2000 mg dailyi (n=178) from a mean baseline A1C of 8.8 percent (p <0.001). The mean placebo-adjusted A1C reductions in the other arms of the study were 1.6 percent with sitagliptin 100 mg daily and metformin immediate-release 1000 mg dailyii (n=183); 1.3 percent with metformin immediate-release 2000 mg dailyiii (n=177); 1.0 percent with metformin immediate-release 1000 mgiv daily (n=178); and 0.8 percent with sitagliptin (n=175), (p<0.001 for all treatment groups versus placebo). At 24 weeks, 66 percent of patients treated with the initial combination of sitagliptin 100 mg daily and metformin immediate-release 2000 mg daily achieved the American Diabetes Association (ADA) goal A1C level of less than 7.0 percent, compared to 38 percent of patients treated with metformin immediate-release 2000 mg daily alone. In the other arms of the study, 43 percent of patients treated with sitagliptin 100 mg daily and metformin immediate-release 1000 mg daily, 23 percent of patients treated with metformin immediate-release 1000 mg daily, and 20 percent of patients treated with sitagliptin achieved the ADA goal A1C level of less than 7.0 percent.

In this study, the incidences of pre-selected gastrointestinal adverse experiences in patients treated with sitagliptin and metformin immediate-release were similar to those reported for patients treated with metformin immediate-release alone.

As clinicians select agents to add to the treatment regimens of patients with type 2 diabetes, it is important to consider issues such as weight gain and hypoglycemia. In this study, the decrease in body weight in the groups given sitagliptin in combination with metformin immediate-release was similar to that in the groups given metformin immediate-release alone or placebo. The overall incidence of reported adverse reactions of hypoglycemia was similar across treatment groups (0.6 percent in patients given placebo, 0.6 percent in patients given sitagliptin alone, 0.8 percent in patients given metformin immediate-release alone, and 1.6 percent in patients given sitagliptin in combination with metformin immediate-release).

The most common adverse reactions reported with sitagliptin and metformin immediate-release as initial therapy (greater than or equal to 5 percent) compared to metformin immediate-release alone were diarrhea (7.5 percent vs. 7.7 percent), upper respiratory infection (6.2 percent vs. 5.2 percent) and headache (5.9 percent vs. 3.8 percent).

JANUMET XR targets three key defects of type 2 diabetes

JANUMET XR targets three key defects of diabetes: insulin deficiency from pancreatic beta cells, insulin resistance, and overproduction of glucose by the liver.

Convenient once-daily JANUMET XR

The dose of JANUMET XR should be individualized on the basis of the patient's current regimen, effectiveness, and

tolerability while not exceeding the maximum recommended daily dose of 100 mg sitagliptin and 2000 mg metformin. Initial combination therapy or maintenance of combination therapy should be individualized and left to the discretion of the health care provider.

In patients not currently treated with metformin, the recommended total daily starting dose of JANUMET XR is 100 mg sitagliptin and 1000 mg metformin HCl extended-release. Patients with inadequate glycemic control on this dose of metformin can be titrated gradually, to reduce gastrointestinal side effects associated with metformin, up to the maximum recommended daily dose.

In patients already treated with metformin, the recommended total daily starting dose of JANUMET XR is 100 mg sitagliptin and the previously prescribed dose of metformin.

For patients taking metformin immediate-release 850 mg twice daily or 1000 mg twice daily, the recommended starting dose of JANUMET XR is two 50 mg sitagliptin/1000 mg metformin HCl extended-release tablets taken together once daily.

Maintain the same total daily dose of sitagliptin and metformin when changing between JANUMET (sitagliptin and metformin HCl immediate-release) and JANUMET XR. Patients with inadequate glycemic control on this dose of metformin can be titrated gradually, to reduce gastrointestinal side effects associated with metformin, up to the maximum recommended daily dose.

JANUMET XR should be administered with food to reduce the gastrointestinal side effects associated with the metformin component.

JANUMET XR should be given once daily with a meal preferably in the evening. Inform patients that JANUMET XR tablets must not be split, broken, crushed, or chewed before swallowing.

The 100 mg sitagliptin/1000 mg metformin HCl extended-release tablet should be taken as a single tablet once daily. Patients using two JANUMET XR tablets (such as two 50 mg sitagliptin/500 mg metformin HCl extended-release tablets or two 50 mg sitagliptin/1000 mg metformin HCl extended-release tablets) should take the two tablets together once daily.

JANUMET XR is available in tablets of 100 mg sitagliptin/1000 mg metformin HCl extended-release, 50 mg sitagliptin/500 mg metformin HCl extended-release, and 50 mg sitagliptin/1000 mg metformin HCl extended-release.

Pricing and availability of JANUMET XR

JANUMET XR is priced comparable to both JANUVIA and JANUMET on a per-daily-dose basis. JANUMET XR will be broadly available in pharmacies in the U.S. in the next several weeks.

Selected risk information for JANUMET XR

Lactic acidosis is a rare, but serious complication that can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure. The onset of lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap and elevated blood lactate. If acidosis is suspected, JANUMET XR should be discontinued and the patient hospitalized immediately.

When lactic acidosis occurs, it is fatal in approximately 50 percent of cases. The reported incidence of lactic acidosis in patients receiving metformin is very low (approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years). Reported cases have occurred primarily in diabetic patients with significant renal impairment, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications.

Patients with congestive heart failure requiring pharmacologic management, in particular those with unstable or acute congestive heart failure who are at risk of hypoperfusion and hypoxemia, are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking JANUMET XR. In particular, treatment of the elderly should be accompanied by careful monitoring of renal function. JANUMET XR treatment should not be initiated in any patient unless measurement of creatinine clearance demonstrates that renal function is not reduced. In addition, JANUMET XR should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis.

Before initiation of JANUMET XR and at least annually thereafter, renal function should be assessed and verified as normal. In patients in whom development of renal dysfunction is anticipated (e.g., elderly), renal function should be assessed more frequently and JANUMET XR discontinued if evidence of renal impairment is present.

Alcohol potentiates the effect of metformin on lactate metabolism. Patients should be warned against excessive alcohol intake while receiving JANUMET XR.

Generally avoid use in patients with hepatic disease. Temporarily discontinue for intercurrent serious conditions, infection, or for any surgical procedures necessitating restricted intake of food or fluids.

Intravascular contrast studies with iodinated materials can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. Therefore, in patients in whom any such study is planned, JANUMET XR should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal.

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JANUMET XR or any other anti-diabetic drug.

The incidence (and rate) of hypoglycemia based on all reports of symptomatic hypoglycemia were: 16.4 percent (0.82 episodes/patient-year) for sitagliptin 100 mg in combination with metformin immediate-release and glimepiride, 0.9 percent (0.02 episodes/patient-year) for placebo in combination with metformin immediate-release and glimepiride, 15.3 percent (0.98 episodes/patient-year) for sitagliptin in combination with metformin immediate-release and insulin and 8.2 percent (0.61 episodes/patient-year) for placebo in combination with metformin immediate-release and insulin.

Adverse reactions with sitagliptin in combination with metformin immediate-release and rosiglitazone through Week 18 were: upper respiratory tract infection (sitagliptin, 5.5 percent placebo, 5.2 percent) and nasopharyngitis (6.1 percent, 4.1 percent). Through Week 54 they were: upper respiratory tract infection (sitagliptin, 15.5 percent; placebo, 6.2 percent), nasopharyngitis (11.0 percent, 9.3 percent), peripheral edema (8.3 percent, 5.2 percent), and headache (5.5 percent, 4.1 percent).

Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but 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.

There have been postmarketing reports of serious hypersensitivity reactions in patients treated with sitagliptin, one of the components of JANUMET XR. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. Onset of these reactions occurred within the first 3 months after initiation of treatment with sitagliptin, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUMET XR, assess for other potential causes for the event, and institute alternative treatment for diabetes.

Use caution in a patient with a history of angioedema to another dipeptidyl peptidase-4 (DPP4) inhibitor because it is unknown whether such patients will be predisposed to angioedema with JANUMET XR.

In clinical studies, the most common adverse reactions reported, regardless of investigator assessment of causality, in ≥5 percent of patients treated with either sitagliptin once daily in combination with metformin immediate-release or placebo were as follows: diarrhea (7.5 percent vs. 4.0 percent), upper respiratory tract infection (6.2 percent vs. 5.1 percent), and headache (5.9 percent vs. 2.8 percent). In patients treated with sitagliptin in combination with metformin immediate-release and sulfonylurea or placebo in combination with metformin immediate-release and sulfonylurea: hypoglycemia (16.4 percent vs. 0.9 percent) and headache (6.9 percent vs. 2.7 percent). In patients treated with sitagliptin in combination with metformin immediate-release and insulin or placebo in combination with metformin immediate-release and insulin: hypoglycemia (15.3 percent vs. 8.2 percent). Other adverse events with an incidence of ≥5 percent included nasopharyngitis for sitagliptin monotherapy and hypoglycemia (13.7% vs. 4.9%) diarrhea (12.5% vs. 5.6%), nausea (6.7% vs. 4.2%), for extended-release metformin vs. placebo when added to glyburide.

Expanding the sitagliptin family of products

Merck is committed to further advancing the medical community's understanding of how to better manage type 2 diabetes, and to providing novel treatment options to people with type 2 diabetes who need them. With JANUVIA, JANUMET, JUVISYNC (sitagliptin and simvastatin) and now JANUMET XR, Merck has a growing family of products that provides physicians with important treatment options for patients with type 2 diabetes.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on Twitter, Facebook and YouTube.

Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in

the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2010 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov).**

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Prescribing Information and Medication Guide for JANUMET® XR are available at **http://www.merck.com/product/usa/pi_circulars/j/janumet_xr/janumet_xr_pi.pdf** and **http://www.merck.com/product/usa/pi_circulars/j/janumet_xr/janumet_xr_mg.pdf.**

1 In this study, sitagliptin and metformin immediate release were administered as separate tablets.

i Sitagliptin 100 mg daily and metformin 2000 mg daily was dosed as sitagliptin 50 mg/metformin 1000 mg twice daily as separate tablets.

ii Sitagliptin 100 mg daily and metformin 1000 mg daily was dosed as sitagliptin 50 mg/metformin 500 mg twice daily as separate tablets.

iii Metformin 2000 mg daily was dosed as metformin 1000 mg twice daily.

iv Metformin 1000 mg daily was dosed as metformin 500 mg twice daily.

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