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**Data Presented at the International Diabetes Federation World Congress  
Compares JANUMET™ (sitagliptin/metformin HCl) to Metformin Alone as Initial  
Therapy**

MONTREAL, October 22, 2009 – New data presented today at the 20<sup>th</sup> World Diabetes Congress of the International Diabetes Federation (IDF) compared two strategies for the initiation of treatment for patients with type 2 diabetes. In the first phase (18 weeks), the treatment effects of JANUMET™ (a fixed-dose combination of sitagliptin and metformin) and metformin as initial therapy were compared. In the second phase (26 weeks), the treatment strategies of initiating sitagliptin/metformin versus initiating metformin were compared (investigators used their clinical discretion, based upon glucose and HbA1c<sup>i</sup> values, to add other diabetes treatments when necessary to achieve blood sugar control). At the end of this 44-week study, mean HbA1c reductions were consistent with those observed at week 18 (-2.4 percent JANUMET vs. -1.8 percent metformin), the primary end point. Patients initially treated with sitagliptin/metformin achieved greater mean HbA1c reductions at 44 weeks compared with those initially treated with metformin (-2.3 percent vs. -1.8 percent) even after physicians were encouraged to add other therapies to help patients achieve target blood sugar goals<sup>ii</sup>.

Metformin is the initial medication given to most newly-diagnosed patients with type 2 diabetes with HbA1c <9.0 percent.<sup>iii</sup> However, in patients with marked hyperglycemia (in particular those with HbA1c ≥9.0 percent, which is what this study included), the Canadian Diabetes Guidelines recommend antihyperglycemic agents should be initiated concomitantly with lifestyle management, and consideration should be given to initiating combination therapy with two agents or initiating insulin treatment in symptomatic individuals. The management options recommended in the guidelines of the Canadian Diabetes Association can be used at the physician's discretion.

“Close to half of current type 2 diabetes patients have not achieved adequate blood sugar control,” said Barry J. Goldstein, M.D., Ph.D., Vice President of Clinical Research,

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Diabetes and Obesity, Merck & Co., Inc. "The significance of this study is that those starting treatment with JANUMET achieved greater HbA1c reductions after 44 weeks compared with those starting treatment with metformin. These findings support the initial use of combination therapy for appropriate patients at diagnosis with type 2 diabetes."

In Canada, JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus inadequately controlled on metformin or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is not indicated for initial combination therapy.

### **About the Study<sup>ii</sup>**

This large, randomized, double-blind study of initial therapy with the fixed dose combination of sitagliptin/metformin compared to metformin alone included 1,246 patients with 625 patients randomized to sitagliptin/metformin and 621 patients randomized to metformin. Doses were titrated over 4 weeks to a maximum dose of 50/1000 mg sitagliptin/metformin twice daily or metformin 1000 mg twice daily<sup>ii</sup>.

This study consisted of two phases. In the first phase (18 weeks), the treatment effects of sitagliptin/metformin and metformin as initial therapy were compared. In the second phase (26 weeks), investigators used their clinical discretion, based upon glucose and HbA1c values, to add other diabetes treatments to the regimen of study participants taking either sitagliptin/metformin or metformin when necessary to achieve blood sugar control<sup>ii</sup>.

At week 18 of this 44-week study, patients taking sitagliptin/metformin achieved mean HbA1c reductions of 2.4 percent from a baseline of 9.9 percent, compared with a reduction of 1.8 percent from a baseline of 9.8 percent for patients taking metformin alone ( $p < 0.001$ )<sup>ii</sup>.

At the conclusion of the study (week 44), patients taking sitagliptin/metformin as initial therapy achieved mean HbA1c reductions of 2.3 percent, compared with 1.8 percent for patients taking metformin, resulting in a significant between-group difference of 0.5 percent ( $p < 0.001$ )<sup>ii</sup>.

In addition, 46 percent of patients achieved HbA1c levels at the Canadian Diabetes Association goal of 7.0 percent or less with sitagliptin/metformin compared with 30 percent of patients treated with metformin, a difference of 50 percent between the treatment groups ( $p < 0.001$ ). Further, 28 percent of patients achieved the International Diabetes Federation goal of less than 6.5 percent with sitagliptin/metformin compared to 17 percent of patients treated with metformin ( $p < 0.001$ )<sup>ii</sup>.

Additional antihyperglycemic treatment was initiated by the investigators in this second phase of the study nearly twice as often in the metformin group compared with the sitagliptin/metformin group (16.7 percent vs. 8.8 percent of patients, respectively)<sup>ii</sup>.

Prespecified adverse events of special interest included hypoglycemia and selected

gastrointestinal-related adverse events (abdominal pain, nausea, vomiting, and diarrhea). The incidence of hypoglycemia was 3.0 percent for sitagliptin/metformin vs. 3.7 percent for metformin. The incidences of selected gastrointestinal-related adverse events for patients taking sitagliptin/metformin, compared to patients taking metformin, were: abdominal pain (3.0 percent vs. 5.3 percent); diarrhea (13.8 percent vs. 18.0 percent); nausea (5.9 percent vs. 7.1 percent) and vomiting (3.0 percent vs. 2.9 percent). Patients in both groups experienced similar effects on weight (-1.1 kg sitagliptin/metformin; -1.2 kg metformin)<sup>ii</sup>.

#### **About Merck & Co., Inc.**

Merck & Co., Inc. (Whitehouse Station, N.J., U.S.A.), which operates in Canada as Merck Frosst Canada Ltd, is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, the Company 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 its 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](http://www.merck.com).

#### **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, 2008, and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

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Product Monograph is available at [www.merckfrosst.com](http://www.merckfrosst.com) .

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<sup>i</sup> HbA1c is a measure that reflects a person's average blood glucose over a two-month to three-month period.

<sup>ii</sup> Olansky L., et al. A Strategy Implementing Initial Therapy with a Fixed-Dose Combination Tablet of Sitagliptin and Metformin in Patients with Type 2 Diabetes Provides Superior Glycemic Control Compared with a Strategy Using Initial Metformin Monotherapy Over 44 Weeks. IDF 20<sup>th</sup> World Diabetes Congress, October 22, 2009.

<sup>iii</sup> Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2008 clinical practice guidelines for the prevention and management of diabetes in Canada. *Can J Diabetes*. 2008;32(suppl 1):S1-S201.