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Merck's Investigational MK-0524 Significantly Reduced Flushing Caused By Extended-Release Niacin in Phase II Study

WHITEHOUSE STATION, N.J.--(HSMN NewsFeed)--In data presented today at the American Heart Association's Scientific Sessions 2006 in Chicago, coadministration of MK-0524, Merck & Co., Inc.'s investigational DP1-receptor antagonist, with extended-release niacin (ERN) significantly reduced flushing in patients with dyslipidemia compared to those patients who took ERN alone. Flushing, characterized by redness of the skin with warming or burning on the face and neck caused by the dilation of blood vessels near the skin, is a common niacin-induced side effect that can cause discomfort to patients and is a significant factor leading to discontinuation of niacin therapy. Merck is developing MK-0524A, an investigational compound that combines Merck's own extended-release niacin with MK-0524, with the intent to deliver niacin in a pill with reduced flushing. MK-0524A is currently in Phase III clinical trials for use as monotherapy or when administered with a statin.

"Previous outcomes studies have shown that niacin has proven efficacy in reducing cardiovascular events and favorable effects on HDL cholesterol and triglyceride levels. It has been frustrating because its use has been limited by flushing," said Christie M. Ballantyne, M.D., associate chief and professor of medicine, Baylor College of Medicine, and co-author of the study. "These data demonstrated that MK-0524 significantly decreased the incidence and intensity of the flushing that occurred in many patients taking extended-release niacin compared to that experienced by patients taking extended-release niacin plus placebo."

About the study

In the eight-week Phase II study, 412 patients with dyslipidemia were randomized to one of four groups: ERN 1 g (given as Niaspan®); ERN 1 g plus MK-0524; ERN 1 g plus placebo; or double placebo; daily for four weeks, with doubling of the respective doses for the remaining four weeks. After starting treatment, patients reported flushing intensity in an electronic diary using the validated numerical and descriptive 11-point Global Flushing Severity Score (none (GFSS 0), mild (1-3), moderate (4-6), severe (7-9) or extreme (10)).

All doses of MK-0524 plus ERN were effective in significantly reducing flushing intensity during both the initiation phase (week 1) and maintenance phase (weeks 2 to 8) when compared to patients taking ERN alone. During the first week of therapy with ERN alone, 61 percent of patients (42/69) reported clinically significant moderate, severe or extreme flushing (GFSS greater than or equal to 4) compared to 37 percent of patients (97/266) treated with ERN administered with MK-0524 (pooled data from all doses). Thirteen percent of patients (9/67) treated with double placebo experienced moderate or worse flushing. During the maintenance phase (weeks 6 to 8), the rate of moderate or severe ERN-induced flushing for patients treated with MK-0524 given with ERN was similar to patients treated with placebo.

Over the eight-week treatment period, lipids were very favorably affected; MK-0524 plus ERN increased HDL-cholesterol by 22.9 percent and reduced LDL-cholesterol and triglycerides by 13.2 percent and 26.5 percent, respectively. There was no difference in lipid response when MK-0524 with ERN was compared to treatment with ERN alone. There was a low incidence of adverse experiences in this study.

Ongoing clinical program

"MK-0524A is currently being studied in a large Phase III program. Merck's commitment to the development of MK-0524A is supported by our ongoing clinical program, which includes a cardiovascular events outcomes study and a newly announced surrogate endpoint study," said John F. Paolini, M.D., Ph.D., senior director clinical research, cardiovascular disease, Merck & Co., Inc. Late-stage clinical trials to support MK-0524B continue, with MK-0524A coadministered with simvastatin, as the Company continues to work on developing the fixed-dose combination formulation.

Merck has recently begun screening patients for ACHIEVE (An Assessment of Coronary Health Using an Intima-Media Thickness Endpoint for Vascular Effects Study), a 2-year multinational carotid ultrasound study in 900 patients with heterozygous familial hypercholesterolemia to assess the effect of MK-0524A on the change in carotid artery intima-media thickness. Patients will receive intensive LDL-cholesterol lowering therapy throughout the study and will be randomized to receive MK-0524A or placebo at 2 g/day for up to 96 weeks.

As previously announced, in early 2007, investigators will begin screening patients with vascular disease into the HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) study to investigate whether MK-0524A can further reduce the risk of heart attacks, strokes, and revascularization procedures among people who are already being treated to lower their LDL, or "bad" cholesterol levels. The researchers also will be examining the long-term safety of MK-0524A.

A total of 20,000 men and women aged 50 to 80 years with a history of heart attack, stroke, peripheral arterial disease, or other coronary disease in the presence of diabetes are being recruited in three regions: the UK (7,500), China (7,500) and Scandinavia (5,000 from Denmark, Norway, Finland and Sweden). Up to 7,000 patients in the study will have diabetes. HPS2-THRIVE is being coordinated at Oxford University by the Clinical Trial Service Unit (CTSU), with a grant from Merck.

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.

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.

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