New Indication for SINGULAIR® (montelukast sodium) Approved to Prevent Exercise-Induced Bronchoconstriction

Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved a new indication for SINGULAIR® (montelukast sodium) to prevent exercise-induced bronchoconstriction (EIB; also known as exercise-induced asthma) in patients aged 15 years and older. SINGULAIR is the first and only oral tablet approved for this use.

Whitehouse Station, N.J. (PRWEB) April 26, 2007 -- Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved a new indication for SINGULAIR® (montelukast sodium) to prevent exercise-induced bronchoconstriction (EIB; also known as exercise-induced asthma) in patients aged 15 years and older. SINGULAIR is the first and only oral tablet approved for this use.

EIB is typically characterized by shortness of breath, cough, wheeze and chest tightness brought on by exercise. "EIB affects a broad spectrum of the asthma population. EIB limits the ability to participate in exercise or physical activities," said David S. Pearlman, M.D., Colorado Allergy and Asthma Centers, P.C. "This indication for SINGULAIR offers physicians a new and effective option to treat appropriate patients with EIB. Asthma is a complex disease, and a variety of treatment options are needed to manage different patients."

In clinical studies, a single tablet of SINGULAIR 10 mg prevented EIB when taken two hours before exercise. Some patients were protected from EIB at 8.5 and 24 hours after administration; however, some patients were not. SINGULAIR should not be taken for the immediate relief of asthma attacks. Patients should always have their inhaled rescue medicine available.

In addition to now being approved for use prior to exercise in appropriate patients with EIB, SINGULAIR continues to be an option for the prevention and chronic treatment of asthma in adults and pediatric patients 12 months of age and older. Patients already taking one tablet daily for another indication, including chronic asthma, should not take an additional dose to prevent EIB. Daily administration of SINGULAIR for the chronic treatment of asthma has not been established to prevent acute episodes of EIB.

SINGULAIR prevented EIB in clinical studies

The efficacy of SINGULAIR 10 mg when given as a single dose two hours before exercise for the prevention of EIB was evaluated in three randomized, double-blind, placebo-controlled crossover studies in 160 patients aged 15 years and older with EIB. In these studies, the primary endpoint was the mean maximum percent fall in FEV1 (Forced Expiratory Volume in the first second -- an important measure of pulmonary function) following exercise at two hours after dosing.

In one study, patients exercised two hours, 8.5 hours and 24 hours after taking either a single 10-mg dose of SINGULAIR or placebo. In this study, a single dose of SINGULAIR 10 mg demonstrated a statistically significant protective benefit against EIB when taken two hours prior to exercise. Some patients were protected from EIB at 8.5 and 24 hours after administration; however, some patients were not. Results in this study were representative of the results from the other two studies.

The safety profile of SINGULAIR in these EIB studies was consistent with the safety profile previously

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Dosage and administration for EIB in patients 15 years of age and older
For prevention of EIB, a single dose of SINGULAIR should be taken at least two hours before exercise. An additional dose of SINGULAIR should not be taken within 24 hours of a previous dose. Patients already taking one tablet daily for another indication (including chronic asthma) should not take an additional dose to prevent EIB. All patients should have inhaled rescue medication available. Safety and effectiveness of SINGULAIR for EIB in patients younger than 15 years of age have not been established. Daily administration of SINGULAIR for the chronic treatment of asthma has not been established to prevent acute episodes of EIB.

Important information about SINGULAIR
SINGULAIR is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older, for the relief of symptoms of seasonal allergic rhinitis (SAR) in adults and children two years and older, and for the relief of symptoms of perennial allergic rhinitis (PAR) in adults and children six months and older. SINGULAIR is indicated for prevention of EIB in patients 15 years of age and older.

The use of SINGULAIR for chronic treatment of asthma may not eliminate the need for inhaled or oral corticosteroids. While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, SINGULAIR should not be abruptly substituted for inhaled or oral corticosteroids. Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking SINGULAIR. Patients should be advised to take SINGULAIR daily as prescribed for chronic treatment of asthma even when they have no symptoms, as well as during periods of worsening asthma, and to contact their physician if their asthma is not well controlled. Patients taking SINGULAIR daily for chronic asthma or allergic rhinitis should speak to their physician about treatment for their EIB.

About exercise-induced bronchoconstriction (EIB)
EIB is a condition typically found in patients with asthma. During bronchoconstriction induced by exercise, the smooth muscle that surrounds the airways in the lungs contracts, narrowing the airways and blocking the flow of air. This may be due to loss of heat, water or both from the lungs as breathing becomes deeper and faster during exercise. However, the underlying mechanism of EIB remains the subject of active scientific investigation. Typically, EIB starts after several minutes of physical activity and reaches peak five to 10 minutes after exercise, usually resolving spontaneously to some degree within an hour.

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 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.
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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Contact Information
Amy Rose
SINGULAIR Merck
http://www.singulair.com
908-423-6537

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