



**FOR IMMEDIATE RELEASE**

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**Merck Statement in Response to the FDA's Update  
Regarding a Safety Review of SINGULAIR® (montelukast)**

WHITEHOUSE STATION, N.J., Jan. 13, 2009 – Merck & Co., Inc. issued the following statement in response to the U.S. Food & Drug Administration's (FDA's) update on its safety review of SINGULAIR® (montelukast).

Merck stands by the proven efficacy and safety of SINGULAIR, a medicine that has been prescribed to tens of millions of patients with asthma and allergic rhinitis for more than 10 years. Nothing is more important to Merck than the safety of its medicines and vaccines.

Since distribution of the "FDA Early Communication of an Ongoing Safety Review of Monelukast" on March 27, 2008, the FDA requested that Merck conduct additional evaluations of the data from clinical trials of SINGULAIR for reports of behavior and mood changes, and for reports of suicidality and suicide. Merck has submitted the information requested by the Agency and is preparing to publish the data in a peer-reviewed medical journal.

Merck also continually reviews post-marketing reports as part of its ongoing commitment to monitor the safety profile of its medications.

After a thorough review of the data from the controlled clinical trials of SINGULAIR, and a careful assessment of post-marketing adverse events, Merck believes that the data support the continued use of SINGULAIR in appropriate patients with asthma and allergic rhinitis.

Merck agrees with the FDA's statement that the data from clinical trials do not suggest that SINGULAIR is associated with suicide or suicidal behavior, although these clinical trials were not designed specifically to examine neuropsychiatric events. In the suicidality analysis submitted to the FDA, which included 9,929 patients who received SINGULAIR and 7,780 patients who received placebo, there was one adjudicated event of suicidal ideation in one patient (an adult treated with SINGULAIR). There were no completed suicides, suicide attempts

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or preparatory acts toward suicidal behavior in the group who received SINGULAIR or the group who received placebo.

In the behavior and mood change analysis, which included 11,673 patients who received SINGULAIR and 8,827 patients who received placebo, the incidence of patients with at least one behavior-related adverse experiences (BRAE) was 2.73 percent and 2.27 percent in the SINGULAIR and placebo groups, respectively (OR 1.12 (95 percent CI [0.93; 1.36])). [Note: Odds ratio (OR) is a statistic to compare the rate of an event between two groups, and the confidence interval (CI) estimates whether those rates are similar or different. If 1.0 falls between the 95 CI values, there is 95 percent confidence that the rates seen in the two groups are not different.] The FDA is continuing to review these clinical trial data. More detail on these analyses is provided below.

Merck will continue communicating with patients, parents and health care providers about SINGULAIR in ways that will help inform their decisions about appropriate treatment choices.

Patients and parents of children with asthma or allergies should talk with their doctors if they have any questions about the benefits and risks of SINGULAIR. They can also visit [www.singulair.com](http://www.singulair.com) for more information. Because asthma is a serious condition, patients should not stop taking the medication without first discussing with their or their child's doctor.

### **Background on analyses for SINGULAIR recently submitted to FDA**

The recently submitted analyses from double-blind, randomized, placebo-controlled clinical studies submitted to the FDA fall into two categories - suicidality analyses and behavior-related adverse experiences (BRAE) analyses.

The suicidality analyses included data from 41 studies conducted in patients aged 6 years and older. The means of analyzing the data and confirming reported events that were used in these analyses were similar to those used by the FDA for other medications. This methodology was independently developed by experts at Columbia University (Columbia Classification Algorithm of Suicide Assessment [C-CASA]).

The BRAE analyses contained data from 46 studies conducted in patients aged 3 months and older. Behavior-related adverse experiences fall under a broad list of mood, behavior and psychiatric reporting terms agreed to with the FDA. The terms used were derived from several standard independent medical dictionaries that are used to categorize adverse experiences.

### **Background on post-marketing adverse event reports for SINGULAIR**

Merck reviews post-marketing adverse event reports for SINGULAIR as part of its ongoing commitment to monitor the medication's safety profile. Merck submits these reports to

the FDA and regulatory agencies in other countries for their review. In addition to reports that Merck receives directly from healthcare providers and patients or their caregivers, we review information published in the medical literature and gather adverse event reports through data obtained directly by the FDA and other regulatory agencies worldwide. Each report is individually reviewed. The fact that an adverse event has been reported does not reflect a conclusion that the post-marketing event is caused by SINGULAIR. In general, a post-marketing adverse event may be caused by underlying disease, genetic condition, the medication, concomitant medications or background event that may occur coincidentally in any population.

The number of adverse event reports per month among U.S. patients taking SINGULAIR sent directly to Merck increased in March 2008 and peaked in April, the time period immediately following the issuance of the FDA Early Communication, and by November and December of 2008 had returned to a level comparable to the rate before the Early Communication was issued. The increase was driven primarily by reports of psychiatric adverse events. Merck believes the increased reporting of these events was due to the extensive media coverage of the FDA Early Communication. This is a recognized phenomenon that can occur following increased attention to a particular medicine or potential adverse event. Many of the reports were for events that had occurred in previous years. Merck has analyzed these reports closely, and believes that the reports received do not change the safety profile of SINGULAIR.

As referenced in the FDA Early Communication, Merck "updated the prescribing information and patient information for SINGULAIR to include the following post-marketing adverse events: tremor (March 2007), depression (April 2007), suicidality (suicidal thinking and behavior) (October 2007), and anxiousness (February 2008)." These updates were undertaken by Merck prior to the FDA's issuance of the FDA Early Communication on March 27, 2008.

Merck encourages healthcare providers and consumers to report any adverse experience associated with any Merck medication or vaccine. Physicians can report adverse events through their Merck sales representative, the Merck National Service Center (1-800-444-2080), or FDA MEDWatch ([www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088). Patients can report adverse events through their healthcare provider, the Merck National Service Center, or FDA MEDWatch.

### **About SINGULAIR**

SINGULAIR is indicated for the prevention 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 2 years and older, and for the relief of symptoms of perennial allergic rhinitis (PAR) in adults and children 6 months 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 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.

In clinical studies in patients with asthma, adverse events were generally mild and varied by age. The most common adverse events in clinical trials in adults and adolescents with asthma ages 15 years and older were headache, influenza, abdominal pain, cough and dyspepsia. In clinical studies in patients with allergic rhinitis, SINGULAIR was generally well tolerated with a safety profile similar to placebo. The most common adverse events in these clinical trials included sinusitis, upper respiratory infection, sinus headache, cough, epistaxis, headache, otitis media, pharyngitis and increased alanine aminotransferase (ALT).

The prescribing information and patient product information for SINGULAIR is attached.

**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, 2007, 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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**Prescribing information and patient product information for SINGULAIR® is attached.**