



American Lung Association Study Finds No Evidence of Depression or Suicide Linked to Asthma and Allergy Drug Montelukast

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WASHINGTON, D.C., Embargoed until September 1, 2008 — There has been recent concern that suicide may be a complication of montelukast (Singulair) therapy. Montelukast is a Food and Drug Administration (FDA) approved oral drug that has been prescribed for more than a decade for the treatment of asthma and seasonal allergy symptoms. An independent study sponsored by the American Lung Association has found no evidence of depression or suicide linked to Montelukast.

American Lung Association researchers Janet Holbrook, PhD, MPH and Raida Harik-Khan, PhD have re-analyzed data from patients who had participated in past clinical trials involving montelukast conducted by the Association's Asthma Clinical Research Centers (ACRC) Network to identify any signals that might suggest a link between montelukast and its effect on emotional well-being. They report their findings in an upcoming issue of the *Journal of Allergy and Clinical Immunology*.

" Discovering adverse effects of a drug after it is on the market can be very difficult, because the data are usually gathered from single events reported by doctors, which makes it is challenging to differentiate actual side effects from events unrelated to the drug," said Norman Edelman, MD American Lung Association Chief Medical Officer. "The value of this 'look back' study is that the investigators were able to compare a large group of patients given montelukast with those given a placebo making a firm scientific conclusion possible."

Holbrook and Harik-Khan reviewed quality of life and emotional well being data collected from patients in three American Lung Association ACRC Network clinical trials that had used montelukast as one of their treatments. Of the 1,352 patients who participated in the double-blind, controlled studies, 569 of these patients had been randomly assigned to take montelukast. The researchers analyzed these patients' data and found no evidence of any deterioration of emotional well being in either the adults or the children who received montelukast. On the contrary, the research team found a positive effect on emotional outlook when comparing patients taking montelukast to those receiving placebo.

While the findings of this study are reassuring and produced no evidence to support the recent publicity regarding a link between montelukast and depression or suicide, the authors do not dismiss the possibility that there could be other unrecognized adverse reactions to montelukast. [View the table of Quality of Life Scores](#) from 3 American Lung Association Asthma Clinical Research Center Trials.

The ACRC Network is an American Lung Association-sponsored research program that conducts large scale clinical trials with the mission of advancing the care and treatment of people with asthma. The network, with a central data coordinating center and 20 clinical centers located across the country, is the largest of its kind. By placing its clinical centers around the country, the ACRC Network is able to enroll large numbers of patients for clinical trials, thus ensuring relevant research findings can be interpreted with the highest level of scientific authority.

Norman Edelman, MD disclosed stock ownership with Johnson & Johnson. Janet Holbrook, PhD, MPH made the following disclosures: Research support by Takeda and Astra-Zeneca; Raida Harik-Khan, PhD had no disclosures.

The American Lung Association has a strict policy of not endorsing products. Corporate and educational partnerships affiliated with the Association's National Headquarters can be found [here](#).

About the American Lung Association: Beginning our second century, the American Lung Association is the leading organization working to prevent lung disease and promote lung health. Lung disease death rates are currently increasing while other major causes of death are declining. The American Lung Association funds vital research on the causes of and treatments for lung disease. With the generous support of the public, the American Lung Association is "*Improving life, one breath at a time.*" For more information about the American Lung Association, a Charity Navigator *Four Star Charity*, or to support the work it does, call 1-800-LUNG-USA (1-800-586-4872) or log on to www.lungusa.org.