Joint statement on FDA investigation of Singulair from the ACAAI and AAAAI

ARLINGTON HEIGHTS, IL - Leadership from the American College of Allergy, Asthma & Immunology and the American Academy of Allergy Asthma & Immunology today released the following statement in response to the Thursday announcement of a Food and Drug Administration investigation into Singulair: There are no data from well-designed studies to indicate a link between Singulair and suicide. The concern expressed by the FDA is based entirely on case reports and there is no indication that such effects apply to other leukotriene-modifying medications.

Post-marketing case reports are incomplete. Furthermore, comparative data are lacking on the incidence of suicide in the general population versus the incidence in patients taking Singulair. Thus, it is unknown whether there is an increased incidence of suicide in patients receiving Singulair. Based on the information currently available, patients taking Singulair should continue to take the medication as prescribed provided: 1) the patient and physician feel the medication is effective; and 2) the patient does not experience any suicidal behavior or thoughts.

Patients who experience suicidal thoughts or demonstrate suicidal behavior should consult their physician immediately to discuss whether to continue with this medication. Patients should not hesitate to consult their physician if they feel uncomfortable continuing on the medication.

American Academy of Allergy Asthma & Immunology (AAAAI) - For immediate release, December 19, 2007

Menopausal women may have an increased asthma risk, from the Journal of Allergy and Clinical Immunology.

MILWAUKEE-Menopause is associated with lower lung function and more respiratory symptoms, especially among lean women, according to a new study in the Journal of Allergy and Clinical Immunology (JACI). The study, “Lung function, respiratory symptoms, and the menopausal transition,” can be found in the articles in press section of the JACI Web site, www.jacionline.org. The JACI is the peer-reviewed journal of the American Academy of Allergy, Asthma & Immunology (AAAAI).

Francisco Gómez Real, MD, and colleagues studied a group of women aged 45-56 years who were not taking sex hormones. The women provided information about their lung health and menstrual history and the ratio of height to weight, body mass index (BMI).

The researchers found:

• Women who had stopped menstruating had significantly lower lung function and more respiratory symptoms than women of the same age who were menstruating regularly.

• Lean women (BMIs of less than 23 kg/m²) showed a greater risk for lung problems. The authors speculate that lower lung function in menopausal women could be explained by increased insulin resistance in menopause. Furthermore, because insulin resistance is a proinflammatory condition, this could also explain the increase in respiratory symptoms associated with menopause. Clinicians should be aware of increased asthma risk and lower lung function in women, especially lean women, reaching menopause.