

March 28, 2008

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

The Food and Drug Administration announced Thursday an investigation into a possible link between Singulair and behavior/mood changes, suicidal thoughts or suicide. This follows an October, 2007 update by Merck and Co., Inc. to include suicidal behavior and thoughts in the prescribing information for Singulair.

The American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology recognize that members may need information and guidance to answer questions from patients or the media. A task force composed of representatives from both organizations met this morning to develop the following joint statement, which was subsequently approved by leadership. We wish to thank members of this group for their responsive time and expertise. These physicians include: David A. Khan, MD, Richard Nicklas, MD, Stanley Szefer, MD and Stephen A. Tilles, MD.

Statement:

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.

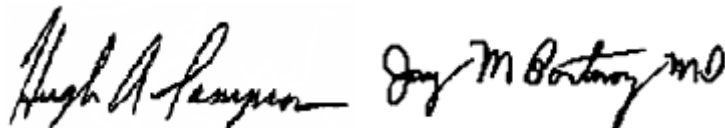
Post-marketing case reports are incomplete. Furthermore, comparative data are lacking on the incidence of suicide in the general population versus the incidence in patients taking Singulair. Thus, it is unknown whether there is an increased incidence of suicide in patients receiving Singulair.

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.

As always, it is important to carefully monitor patients on any medication and specifically inquire about any adverse events.

Due to the complexity of the FDA analysis, the agency has stated that it could take up to nine months before it can draw any conclusions. At that point, hopefully, more information will be conveyed to the public.



Hugh A. Sampson, MD, FAAAAI
AAAAI President

Jay M. Portnoy, MD, FACAAI
ACAAI President