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Asthmatx Receives FDA Advisory Panel Recommendation for Approvable with Conditions for Bronchial Thermoplasty with the Alair® System for Severe Asthma

GAITHERSBURG, Md. – October 28, 2009 – Asthmatx Inc., announced today that the Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee to the U.S. Food and Drug Administration (FDA) voted to recommend that the Alair® System, a device utilized in bronchial thermoplasty for the treatment of severe persistent asthma in patients 18 years and older, be found approvable with conditions.

The Anesthesiology and Respiratory Therapy Devices Panel voted 6 to 1 in favor of approvable with conditions, which were primarily related to labeling and post-approval studies. The final decision regarding the approval of the device is made by the FDA and while the FDA is not required to follow the advice of its advisory committee, it generally does.

“The Advisory Panel’s recommendation for approvable with conditions of the Alair System marks a major step in bringing this new and important treatment option to patients with severe asthma,” said Glen French, CEO of Asthmatx. “We look forward to working with FDA through the next steps to product approval.”

Bronchial thermoplasty is a novel, non-drug procedure developed to treat adults with severe asthma and is designed to provide improved asthma quality of life and control that lasts for at least one year. Bronchial thermoplasty delivered by the Alair System uses thermal energy to reduce the muscle associated with airway constriction in asthma patients. The Committee reviewed the results of the AIR2 Trial, which found that in the year following bronchial thermoplasty, treated patients with severe asthma experienced the following benefits:

- Significant improvement in quality of life
- 32 percent reduction in severe asthma attacks
- 84 percent reduction in emergency room visits for respiratory symptoms
- 66 percent reduction in days lost from work/school or other activities

“Asthma is a serious public health problem. For many patients with severe asthma, even high doses of standard of care medications taken daily do not prevent frequent asthma attacks, which can be life-threatening,” said Mario Castro, MD, Professor of Medicine at the Washington University School of Medicine, who presented data on the AIR2 Trial as the principal investigator. “We are hopeful that the FDA will concur with the recommendation made by the Panel today to make this procedure available to patients with severe asthma who have an enormous unmet medical need.”

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In the period immediately following bronchial thermoplasty, there is an expected transient increase and worsening of respiratory-related symptoms, which are of the type expected following bronchoscopy in patients with asthma. These events typically occur within a day of the procedure and resolve on average within seven days with standard care. In the long term, fewer bronchial thermoplasty treated patients reported respiratory adverse events and there was a significant decrease in patients reporting asthma (multiple symptoms) adverse events in the Alair-treated group compared to the sham control group.

About Bronchial Thermoplasty Delivered by the Alair System
Bronchial thermoplasty is a non-drug procedure for asthma. The treatment is performed through the working channel of a standard flexible bronchoscope that is introduced through a patient's nose or mouth and into their lungs. The tip of the small diameter Alair catheter is expanded to contact the walls of targeted airways. Controlled thermal energy is then delivered to the airway walls to reduce the presence of airway smooth muscle that narrows the airways in patients with asthma. The minimally invasive procedure, like many other flexible endoscopy procedures, is done under light anesthesia, and the patient returns home the same day.

CAUTION: The Alair System is an Investigational Device. It is limited by United States law to investigational use. To be used by Qualified Investigators only.

About Asthmatx
Asthmatx is developing catheter-based medical devices for the treatment of asthma. Asthmatx has developed the Alair System to perform an investigational outpatient procedure called bronchial thermoplasty. The Alair System has received a CE Mark for use in the European Union. For more information on Asthmatx visit www.asthmatx.com.

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