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Asthmatx Pivotal Trial Manuscript for Bronchial Thermoplasty Published in the American Journal of Respiratory and Critical Care Medicine

Bronchoscopic Procedure to Treat Severe Asthma Found to Improve Asthma Control by Reducing Asthma Attacks and Emergency Room Visits, and Improving Asthma Quality of Life

SUNNYVALE, Calif. (January 12, 2010) -- Asthmatx Inc., developer of bronchial thermoplasty with the Alair[®] System, announced today the publication of positive results from its pivotal study, the Asthma Intervention Research 2 (AIR2) Trial, in the *American Journal of Respiratory and Critical Care Medicine (AJRCCM)*. The publication, entitled "Effectiveness and Safety of Bronchial Thermoplasty in the Treatment of Severe Asthma: A Multicenter, Randomized, Double-Blind, Sham-Controlled Clinical Trial," demonstrated statistically significant reductions in asthma attacks (severe exacerbations) and emergency room visits for respiratory symptoms, as well as improvements in quality of life in adults with severe asthma who underwent bronchial thermoplasty with the Alair System.

"Bronchial thermoplasty decreases severe exacerbations and ER visits for respiratory symptoms and improves quality of life in patients with severe asthma," said Mario Castro, MD, Professor of Medicine and Pediatrics at the Washington University School of Medicine, a principal investigator in the AIR2 Trial and the lead author of the paper. "Bronchial thermoplasty with the Alair System offers clinicians a novel adjunctive therapy option, beyond the current use of inhaled corticosteroids and long acting beta agonists, to provide improvements in overall asthma control."

The AIR2 Trial was designed to evaluate the safety and effectiveness of bronchial thermoplasty in adult patients with severe asthma who remain symptomatic, despite treatment with standard of care medications (high dose inhaled corticosteroids and long-acting beta agonists). The study was a randomized, double-blind, sham-controlled trial that enrolled 297 patients at 30 sites in six countries. The primary effectiveness endpoint was the change from baseline in Asthma Quality of Life Questionnaire (AQLQ) score. Safety was assessed by comparing the short and long-term (out to one year) safety profiles for both the active and sham treatment groups.

In addition to an improvement in quality of life as measured by an increase in average Asthma Quality of Life Questionnaire (AQLQ) score at 6, 9, and 12 months in the active compared to the sham group, there were also improvements in overall asthma control as demonstrated by the following key statistically significant clinical findings of the AIR2 Trial during long-term follow-up:

- 32% reduction in asthma attacks
- 84% reduction in emergency room visits for respiratory symptoms



- 66% reduction in days lost from work/school or other activities due to asthma
- 36% reduction in patients reporting worsening of asthma due to multiple symptoms

In the period immediately following bronchial thermoplasty, there was an expected increase and worsening of respiratory-related symptoms, which were of the type expected following bronchoscopy in patients with asthma. These events typically occurred within a day of the procedure and resolved on average within seven days with standard care. In the long term after treatment, fewer bronchial thermoplasty treated patients reported respiratory adverse events. The report in *AJRCCM* concluded that the increased risk of adverse events in the short-term following the procedure is outweighed by the benefit of bronchial thermoplasty that persists for at least one year.

In October of 2009, 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 be found approvable with conditions based on the results of this and other studies. The application for FDA approval of the Alair System is presently under review by FDA.

About Bronchial Thermoplasty Delivered by the Alair System

Bronchial thermoplasty is a bronchoscopic procedure for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. Bronchial thermoplasty 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 moderate sedation, and the patient returns home the same day. For more information on bronchial thermoplasty visit www.bronchialthermoplasty.com.

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

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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 <u>www.asthmatx.com</u>.

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