Asthmatx®

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Asthmatx Receives FDA Approval for the Alair® Bronchial Thermoplasty System

First Approved Non-drug Asthma Treatment Offers Long Lasting Control of Severe Asthma

SUNNYVALE, Calif. (April 27, 2010) – Asthmatx Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved the Alair® Bronchial Thermoplasty System 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, the current standard-of-care treatment for these patients.

Bronchial thermoplasty (BT), which is the first device-based asthma treatment approved by the FDA, is a novel outpatient procedure that delivers precisely controlled thermal energy to reduce excess airway smooth muscle that is associated with airway constriction in patients with asthma. By decreasing the ability of the airways to constrict, this new treatment has been shown to help patients with severe asthma gain substantially better control over their disease.

FDA approval of the Alair System was largely based on the promising results of the AIR2 Trial, a double-blind, randomized study designed to evaluate the safety and effectiveness of bronchial thermoplasty in adult patients with severe asthma. The study was published in the January 15, 2010 issue of the *American Journal of Respiratory and Critical Care Medicine* (*AJRCCM*). Not only did the trial demonstrate that patients treated with the Alair System improve their asthma quality of life over patients who rely solely on medical therapy after one year, but these patients also experience other clinically significant benefits, including:

- 32 percent reduction in asthma attacks
- 84 percent reduction in emergency room visits for respiratory symptoms
- 73 percent reduction in hospitalizations for respiratory symptoms
- 66 percent reduction in days lost from work/school or other daily activities due to asthma

In the period immediately following bronchial thermoplasty, there was an expected transient increase in the frequency 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. Investigators in the AIR2 Trial concluded that the increased risk of adverse events in the short-term following bronchial thermoplasty is outweighed by the benefits, which persist for at least one year.

"Approval of the Alair System for bronchial thermoplasty will enable clinicians to provide a much needed treatment option to their patients with severe asthma," said Mario Castro, MD, Professor of Medicine and Pediatrics at the Washington University School of Medicine, and principal investigator of the AIR2 Trial. "These are patients who, despite receiving high levels of asthma medications, continue to suffer from asthma attacks, which often result in emergency room visits and impose significant limitations on their daily activities. Bronchial thermoplasty offers these patients an important new way to control their disease."

Millions of patients with asthma struggle to keep their disease under control. Asthma accounts for one-quarter of all emergency room visits in the U.S. Each day, roughly 40,000 unscheduled physician office visits, 5,000 emergency room visits, and 1,000 hospitalizations occur due to asthma.

“After more than a decade of careful research and four separate clinical studies, the FDA approval marks the final step in bringing this first-of-its-kind treatment option to patients with an unmet medical need,” said Glen French, CEO of Asthmatx. “We look forward to continuing to work closely with asthma and pulmonary experts to address the needs of patients with this debilitating disease.”

About Asthma
Asthma is one of the most common and costly diseases in the world. The prevalence of asthma has grown in recent decades, and there is no cure. According to the Asthma and Allergy Foundation of America (AAFA), more than 20 million Americans have asthma, and managing asthma consumes over $18 billion of healthcare resources each year. In the U.S. each year, asthma attacks result in approximately 10 million outpatient visits, two million emergency rooms visits, 500,000 hospitalizations and 4,000 deaths.

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 excess 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 typically returns home the same day.

For more information on bronchial thermoplasty and the procedure's availability visit www.bronchialthermoplasty.com.

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About Asthmatx
Based in Sunnyvale, Calif., Asthmatx is a privately-held medical device company that designs, develops and manufactures catheter based medical devices incorporating thermal energy for patients with severe asthma. Asthmatx's first offering, bronchial thermoplasty delivered by the Alair System, is a novel device-based treatment option for patients with severe asthma. The Alair System has been approved for use in the U.S. by the FDA and has received a CE Mark for use in the European Union. For more information on Asthmatx visit www.asthmatx.com.

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