Boston Scientific

The Journal of Allergy and Clinical Immunology Publishes Bronchial Thermoplasty Data Demonstrating Sustained Reduction In Severe Asthma Attacks Over Five Years

NATICK, Mass., Sept. 4, 2013 /PRNewswire/ -- A breakthrough Boston Scientific technology for the treatment of severe asthma has been shown to be safe and effective over at least five years, according to data published online in a key medical journal.

The Journal of Allergy and Clinical Immunology, the official scientific journal of the American Academy of Allergy, Asthma & Immunology (AAAAI) and the most-cited journal in the field of allergy and clinical immunology, featured data from the Asthma Intervention Research 2 (AIR2) clinical trial examining the safety and effectiveness of the Boston Scientific Alair® Bronchial Thermoplasty (BT) System. The long-term data are based on a post-approval study of BT-treated patients from the AIR2 Trial who were followed for a total of five years.

Key findings reported at five years following BT include:

- Reduction in the percentage of BT-treated patients experiencing severe exacerbations (compared to patients treated with a sham control) was maintained out to five years
- Over five years, 48 percent average decrease observed in the rate of severe exacerbations in BT-treated patients compared to the year prior to receiving BT
- Over five years, 88 percent average decrease observed in the rate of emergency room (ER) visits for respiratory symptoms in BT-treated patients compared to the year prior to receiving BT
- Comparison of high resolution computed tomography (HRCT) images before BT and at five years post BT-treatment showed no structural changes in the airways due to BT that were of clinical significance
- No increase in hospitalizations for respiratory symptoms over the course of five years
- No increase in respiratory adverse events over the course of five years
- No difference in the percentage of patients experiencing severe exacerbations, ER visits and asthma symptoms over five years based on patient reported allergy status
- 85 percent of patients who underwent BT treatment in the AIR2 Trial completed the five-year follow-up, demonstrating exceptionally strong patient retention for a study of this complexity and duration

"BT is a major innovation in the treatment of severe asthma," said Michael E. Wechsler, M.D., director of the Asthma Program in the Department of Medicine at National Jewish Health in Denver, an investigator in the AIR2 Trial, and lead author in the publication. "The compelling data from this long-term follow-up now confirm persistence of effect for BT out to at least five years."

Bronchial Thermoplasty, delivered by the Alair System, is a safe, outpatient procedure. The Alair System delivers thermal energy to the airway wall in a precisely controlled manner to reduce excessive airway smooth muscle. It is designed to decrease the ability of the airway to constrict, thereby reducing frequency and severity of asthma attacks. Fewer asthma attacks means less need for the associated oral steroid treatment—and the related side effects.

"Despite great advances over the past few decades in asthma medications, many patients with severe asthma still can't get their disease under control and often have few treatment options other than oral steroids," said Mike Tringale, vice president of external affairs at the Asthma and Allergy Foundation of America (www.AAFA.org). "The potential to provide a long-term reduction in emergency room visits, asthma attacks and their associated need for oral steroid treatment is very important to patients with asthma."

Unlike other currently available therapies for severe asthma that have a short-term effect, a single BT treatment comprising three procedures provides long-term benefit and may lead to long-term savings for that patient, as demonstrated by the sustained reduction in asthma attacks and ER visits out to at least five years.

"There is no other treatment that I have for severe asthma patients that can give you these kinds of long-term benefits," said Mario Castro, M.D., professor of medicine and pediatrics at the Washington University School of Medicine, and principal investigator in the AIR2 Trial. "We have now completed five years of follow-up in three randomized controlled studies. In particular, this long-term study provides the clinical evidence of long-term safety and effectiveness that the asthma community

has been looking for and I strongly believe that patients with severe asthma should have access to this therapy now."

The long-term benefits of Bronchial Thermoplasty, including a reduction in severe exacerbations and emergency room visits, are consistent with the stated goals of asthma control as defined by the National Asthma Education and Prevention Program (NAEPP).

To learn more about Bronchial Thermoplasty, visit www.BTforAsthma.com.

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, more than 20 million Americans have asthma. Managing asthma consumes more than $18 billion of healthcare resources each year in the United States. Uncontrolled asthma results in approximately 10 million unscheduled physician office visits, 2 million ER visits, 500,000 hospitalizations, and 4,000 deaths annually in the U.S. Five to 10 percent of those suffering from asthma in the U.S. are diagnosed with severe persistent asthma.

To view the multimedia assets associated with this release, please click:http://www.multivu.com/mnr/55217-boston-scientific-bronchial-thermoplasty-for-asthma

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