

## **Long-term Safety and Effectiveness of Bronchial Thermoplasty Demonstrated in Treating Severe Asthma**

**Five-year data from RISA Trial presented at ATS adds to clinical evidence showing long-term safety of Boston Scientific's Alair® Bronchial Thermoplasty System**

NATICK, Mass. and DENVER, May 16, 2011 [/PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced long-term safety data from the Research in Severe Asthma (RISA) Trial, which demonstrated the maintenance of stable lung function and the absence of clinical complications over a five-year period in patients with severe refractory asthma treated with its Alair® Bronchial Thermoplasty System. The RISA Trial is the third in a series of clinical trials that have completed five years of follow-up for patients treated with bronchial thermoplasty (BT).

Results were presented at the annual meeting of the American Thoracic Society (ATS) in Denver by Ian Pavord, M.D., Professor of Medicine at the University of Leicester, UK and RISA Trial Principal Investigator.

"With the addition of this new long-term data, I can confidently advise patients whose asthma is poorly controlled with medications that bronchial thermoplasty demonstrates a stable safety profile for at least five years," said Dr. Pavord. "The Alair System offers a novel adjunctive therapy option, beyond use of inhaled corticosteroids and long-acting beta agonists, to provide long-term improvements in overall asthma control."

BT is a bronchoscopic procedure performed under moderate sedation on an outpatient basis. 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 airway's ability to constrict, thereby reducing asthma attack frequency and severity.

The presentation of five-year safety data from the RISA Trial follows two recently published peer-reviewed articles that further support positive long-term outcomes following bronchial thermoplasty:

- In February, the journal *BMC Pulmonary Medicine* published five-year safety data from the AIR Trial, a randomized controlled trial comparing BT to standard of care for patients with moderate to severe asthma. The publication highlighted the absence of clinical complications and the maintenance of stable lung function over a five-year period post-BT, supporting the long-term safety profile of BT.
- The current issue of *Annals of Allergy Asthma & Immunology* includes the article "Persistence of Effectiveness of Bronchial Thermoplasty in Patients with Severe Asthma," which is available at [www.annallergy.org](http://www.annallergy.org). It presents findings from the pivotal Asthma Intervention Research 2 (AIR2) Trial that demonstrate the persistence of safety and effectiveness of BT at two years.

"It is rewarding to see the important benefits of bronchial thermoplasty persist out to two years in patients with severe asthma studied in the AIR2 Trial," said Mario Castro, M.D., Professor of Medicine and Pediatrics at the Washington University School of Medicine, a Principal Investigator in the AIR2 Trial and lead author of the AIR2 paper. "These clinically meaningful improvements, combined with consistent and stable long-term safety, confirm bronchial thermoplasty as an important new treatment option for patients with severe asthma that is poorly controlled with currently available medications."

In summary, bronchial thermoplasty has demonstrated a strong long-term safety profile with follow up out to five years in three consecutive clinical trials. In addition to safety, the two-year results from the AIR2 Trial also demonstrate long-term persistence of effect.

The Alair Bronchial Thermoplasty System, which provides long-lasting and improved asthma control for adult severe asthma patients whose asthma is not well controlled by current drugs (inhaled medications), has been developed by Asthmatx, which was acquired by Boston Scientific in 2010.

### **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, more than 20 million Americans have asthma. Managing asthma consumes more than \$18 billion of healthcare resources each year in the U.S. Uncontrolled asthma results in approximately 10 million unscheduled physician office

visits, 2 million emergency rooms 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

## **About Boston Scientific**

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: [www.bostonscientific.com](http://www.bostonscientific.com).

## **Cautionary Statement Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding new product launches and launch cadence, regulatory approvals, clinical trials, product performance and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements.

These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors.

All of these factors are difficult or impossible to predict accurately and many of them are beyond our control.

For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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