Boston Scientific Long Term Data Demonstrate Bronchial Thermoplasty Treatment Benefits Persist Out to Five Years in Patients with Severe Asthma [EN]

Five-year data from the Asthma Intervention Research 2 (AIR2) clinical trial presented today demonstrated that the Boston Scientific Corporation (NYSE: BSX) Alair® Bronchial Thermoplasty (BT) System continues to show therapy benefits in adult patients with severe uncontrolled asthma. Bronchial Thermoplasty was shown to provide long term asthma control, demonstrated by a sustained reduction in the rate of severe exacerbations (asthma attacks) and emergency room (ER) visits over a five year period after treatment. The AIR2 trial is the fourth in a series of clinical trials that have completed five years of follow-up and the first to evaluate persistence of effect for patients treated with BT. Results were presented at the annual meeting of the American Thoracic Society (ATS) in Philadelphia by Michael E. Wechsler, M.D., director of the Asthma Program in the Department of Medicine at National Jewish Health in Denver and an investigator in the AIR2 trial.

"With the availability of the new long term data demonstrating that the benefits of Bronchial Thermoplasty persist for at least five years, I can confidently recommend BT as a therapeutic option to patients whose asthma is poorly controlled with medications alone," said Dr. Wechsler. "This is very important because minimizing the risk of recurrent asthma attacks and the associated need for oral steroid treatment in this patient population is a primary goal in asthma therapy. Bronchial Thermoplasty represents a one time, long term option for achieving better asthma control in a select population of patients. Left uncontrolled, these patients contribute to a disproportionate share of the costs associated with treating asthma."

The data are based on an open-label study following BT-treated patients who completed the one-year portion of the AIR2 trial for a total of five years. The goal of the study was to demonstrate that the percentage of patients experiencing severe exacerbations over the five years following BT was not substantially worse than the percentage of patients having exacerbations in the first year after BT. The data demonstrated that over five years following BT there was a:

- 44 percent average decrease in percent of patients having severe exacerbations compared to the year prior to BT
- 48 percent average decrease in severe exacerbation event rates compared to the year prior to BT
- 88 percent average decrease in ER visit event rates compared to the year prior to BT

"We are pleased to see the significant benefits of Bronchial Thermoplasty persist out to five years in patients with severe asthma," said David Pierce, president, Endoscopy, Boston Scientific. "These clinically meaningful improvements demonstrate that Bronchial Thermoplasty improves patient outcomes and quality of life. In addition, by significantly reducing health care utilization, Bronchial Thermoplasty presents an opportunity to reduce overall health care costs for asthma." Separately, the Asthma and Allergy Foundation of America (AAFA) recently released its list of 2013 Asthma Capitals, an assessment of the most challenging places to live with asthma in the United States (<u>https://www.asthmacapitals.com</u>). For the first time, this year AAFA added a new factor to the ranking assessment: ER visits for asthma. About five percent of the asthma population is considered to have the most severe form of asthma and often does not respond well to conventional asthma treatments. People with severe asthma are likely to have more asthma attacks, visit ERs or be hospitalized more frequently, and are at greater risk of death.

Bronchial Thermoplasty, delivered by the Alair System, is a safe, outpatient procedure proven to provide a long lasting reduction in asthma attacks and ER visits for patients with severe asthma. 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. Fewer asthma attacks mean less need for the associated oral steroid treatment—and its side effects. To learn more about Bronchial Thermoplasty, visit <u>www.BTforAsthma.com</u>.

In summary, BT is a novel bronchoscopic procedure providing long lasting asthma control that has demonstrated a strong long term safety and efficacy profile out to at least five years in four consecutive clinical trials.

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 United States. Uncontrolled asthma results in approximately 10 million unscheduled physician office visits, two million ER visits, 500,000 hospitalizations and 4,000 deaths annually in the United States. Five to 10 percent of those suffering from asthma in the United States are diagnosed with severe persistent asthma

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit <u>www.bostonscientific.com</u> and connect on <u>Twitter</u> and <u>Facebook</u>.

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 markets for our products, our business plans, 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.

HAFTUNGSAUSSCHLUSS: Bitte beachten Sie, dass es in einigen Staaten der EU (Bulgarien, Zypern, Estland, Frankreich, Griechenland, Ungarn, Irland, Italien, Lettland, Litauen, Luxemburg, Malta, Polen, Portugal, Rumänien, Slowakei, Belgien, Niederlande, Slowenien und Spanien) gegen das Gesetz verstößt, eine Werbung für medizinische Geräte an die allgemeine Öffentlichkeit zu richten. Wenn Sie diese Internetseite aus einem der genannten Länder besuchen und beruflich nicht im Gesundheitswesen tätig sind, sollten Sie den Besuch unverzüglich abbrechen, da Informationen präsentiert werden, deren Ansicht nach nationaler Rechtslage nicht gestattet ist. Sollten Sie diesen Warnhinweis missachten, übernimmt Boston Scientific für etwaige Folgen, die Ihnen aus diesem Zugang entstehen, keine Haftung.

<u>https://news.bostonscientific.eu/2013-05-21-Boston-Scientific-Long-Term-Data-Demonstrate-Bronchial-Thermoplasty-Treatment-Benefits-Persist-Out-to-Five-Years-in-Patients-with-Severe-Asthma-EN</u>