# Boston Scientific's Alair® Bronchial Thermoplasty System Achieves Important Reimbursement Milestones

CMS pass-through payment and new CPT \$[1] codes established for catheter-based procedure to treat severe asthma

NATICK, Mass., Jan. 4, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced that the Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare program, has acknowledged the substantial clinical improvement associated with the use of the Alair® Bronchial Thermoplasty System to perform bronchial thermoplasty for the management of severe asthma. As a result, effective January 1, 2012, the Alair catheter is eligible for Medicare reimbursement through a separate "pass-through" payment when the procedure is performed in an outpatient hospital setting. This pass-through payment will enable hospitals to receive payment for the Alair catheter in addition to Medicare's payment for the bronchial thermoplasty procedure until utilization and payment data are well established. The combined Medicare payments for the device and procedure should provide a strong benchmark for private insurers establishing reimbursement for bronchial thermoplasty.

"CMS' decision that the Alair Bronchial Thermoplasty System meets the criteria for transitional pass-through payment is a very positive development for severe asthmatics and the pulmonary physician community," said David Pierce, President of Boston Scientific's Endoscopy Division. "It supports what we have confirmed through our clinical trials: bronchial thermoplasty offers a new advancement in the treatment of patients with severe asthma who are not well controlled despite taking recommended doses of asthma medications. This decision also sets an important precedent for health care payers throughout the United States."

As of January 1, 2012, hospitals are able to report a special code for the Alair catheter along with one of two new Category III CPT®[1] (current procedural terminology) codes established by the American Medical Association (AMA) for the bronchial thermoplasty procedure that will also be implemented for 2012. The new CPT codes will facilitate specific reporting of bronchial thermoplasty across all payers for the first time since the U.S. Food and Drug Administration (FDA) approved the Alair Bronchial Thermoplasty System for marketing in mid-2010.

"The AMA's creation of new Category III CPT®[2] codes for bronchial thermoplasty represents a critical step toward consistent reimbursement for this ground-breaking procedure. The codes will simplify the process of submitting and adjudicating insurance claims for physicians and hospitals, as well as for asthma patients," said Parashar Patel, Vice President, Global Health Economics and Reimbursement for Boston Scientific. "The decision acknowledges the growing body of peer-reviewed, published clinical literature on bronchial thermoplasty's safety, efficacy and long-term health outcomes, and is the result of significant support from pulmonary specialty societies including the American Thoracic Society, the largest U.S.-based group representing more than 15,000 physicians, research scientists, nurses and other healthcare professionals."

The Alair Bronchial Thermoplasty System is an FDA-approved and CE Marked device used in 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 for patients with severe persistent asthma that is not well controlled with inhaled corticosteroids and long-acting beta-agonists. Clinical trial results, which have been published in peer-reviewed articles, demonstrate safety out to five years and persistence of clinical benefit out to at least two years.

#### **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 United States. Approximately five percent of Americans suffering from asthma 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: <a href="https://www.bostonscientific.com">www.bostonscientific.com</a>.

## **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 Medicare reimbursement and its effects, new CPT codes and their effects, clinical trials and literature, 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.

#### CONTACT:

Eric Olson 336-293-4393 (office) Media Relations Boston Scientific Corporation eric.olson@bsci.com

Sean Findlen 617-520-7268 (office) Media Relations Weber Shandwick sfindlen@webershandwick.com

Sean Wirtjes 508-652-5305 (office) Investor Relations Boston Scientific Corporation investor relations@bsci.com

[1] CPT Copyright 2012 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

[2] CPT Copyright 2012 American Medical Association. All rights reserved.

SOURCE Boston Scientific

https://news.bostonscientific.com/news-releases?item=101911