

## Boston Scientific Alair® Bronchial Thermoplasty System Approved In China



*Alair BT System*

SHANGHAI, Oct. 23, 2013 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received China Food and Drug Administration approval for the [Alair® Bronchial Thermoplasty System](#), an innovative medical device designed to treat severe asthma. Expected to be available in the China market later this year, the Alair System provides a unique and effective therapy for patients with severe asthma which is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

Bronchial Thermoplasty (BT) is a bronchoscopic procedure typically performed under moderate sedation on an outpatient basis. Delivered by the Alair System, BT uses mild heat to reduce the excessive smooth muscle tissue in the airways. This reduces airway constriction during an asthma attack, making attacks less frequent and less severe.

"We are delighted to see that the Boston Scientific Alair® Bronchial Thermoplasty System has been officially certified by the China Food and Drug Administration," said Warren Wang, vice president and managing director-China, Boston Scientific. "Unlike conventional treatments, Bronchial Thermoplasty offers a viable new option for patients suffering from severe asthma thanks to its breakthrough technology and mechanism of action. We believe this device can markedly improve the quality of life of asthma patients here in China."

BT delivered by the Alair System has been proven in clinical trials to be safe and effective. Data from the Asthma Intervention Research 2 (AIR2) Trial, a multi-site, double-blind, sham-controlled study, demonstrated that after undergoing BT treatment, patients reported significant improvement in asthma-related quality of life.<sup>1</sup> Furthermore, the benefit of a single BT treatment performed over three bronchoscopy sessions was shown to persist out to at least five years.<sup>2</sup>

[Key findings from the AIR2 Trial](#) reported at five years 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
- High resolution computed tomography (HRCT) review showed no structural changes in the airways due to BT that were clinically significant
- No increase in hospitalizations, asthma symptoms, or respiratory adverse events over 5 years.

For more information on the Alair® Bronchial Thermoplasty System and AIR2 Trial results, including multimedia assets, please click [here](#).

To learn more about Bronchial Thermoplasty, visit [www.BTforAsthma.com](http://www.BTforAsthma.com).

### **About Bronchial Thermoplasty (BT)**

Bronchial Thermoplasty applies therapeutic radiofrequency/thermal energy to the airway wall to reduce excessive smooth muscle, and help minimize airway constriction. BT, delivered by the Alair® System, is an outpatient procedure performed in three sessions, typically scheduled three weeks apart.

### **About Boston Scientific in China**

Boston Scientific established its China headquarters in Shanghai in 1997 and now has branches and R&D centers in Beijing, Shanghai and Guangzhou. Core Boston Scientific businesses in China include cardiac intervention, cardiac rhythm

management, endoscopic intervention, peripheral interventions and oncology, and urology and women's health. As an R&D leader, the company provides high performance medical products and solutions for the prevention, diagnosis and treatment of assorted diseases and conditions. Boston Scientific strives to provide the most innovative global medical technology that is custom-tailored to fit the needs of Chinese patients.

### **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 [www.bostonscientific.com](http://www.bostonscientific.com) and connect on [Twitter](#) and [Facebook](#).

### **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 our business plans and investments in China, product performance and effects, and the availability of the Alair System in China. 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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<sup>1</sup> Castro et al, AJRCCM 2010

<sup>2</sup> Wechsler et al, JACI 2013, In Press

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