Boston Scientific Alair Bronchial Thermoplasty System Approved In China

PR Newswire

Boston Scientific Corporation 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.[1] Furthermore, the benefit of a single BT treatment performed over three bronchoscopy sessions was shown to persist out to at least five years.[2]

Key findings from the AIR2 Trial [1] 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 [2].

To learn more about Bronchial Thermoplasty, visit www.BTforAsthma.com [3].

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Links:
[1] http://bostonscientific.mediaroom.com/2013-09-04-The-Journal-of-Allergy-and-Clinical-Immunology-Publishes-Bronchial-Thermoplasty-Data-Demonstrating-Sustained-Reduction-In-Severe-Asthma-Attacks-Over-Five-Years
[2] http://www.multivu.com/mnr/55217-boston-scientific-bronchial-thermoplasty-for-asthma
[3] http://www.btforasthma.com/