Boston Scientific

Real-World Data Confirms Long-Term Effectiveness Of Bronchial Thermoplasty

Patients with Severe Asthma Show Sustained Clinical Improvement

MARLBOROUGH, Mass., Sept. 18, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced results from a three year follow-up cohort in its Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty (BT) in Severe Persistent Asthma (PAS2) study. The results showed that the 190 patients in the real-world study achieved similar reductions in severe exacerbations, hospitalizations and emergency room visits when compared to the 190 patients treated with BT in the pivotal randomized, sham-controlled Asthma Intervention Research 2 (AIR2) trial.

The results, which were published in the European Respiratory Journal, the peer-reviewed journal of the European Respiratory Society, corroborate the AIR2 trial and demonstrate that the findings translate into meaningful outcomes in real-world practice. PAS2 study participants had asthma symptoms that were less well-controlled than subjects in the AIR2 trial and results from the study demonstrate that, following the last BT treatment:

- The percentage of patients experiencing severe exacerbations decreased from 74 to 40;
- The percentage of patients with a hospitalization for at least one asthma symptom decreased from 15 to 7 percent;
- The percentage of patients with emergency room visits decreased from 27 to 11; and that
- The percentage of patients using daily maintenance oral corticosteroid medications decreased from 19 to 10.

"The PAS2 study confirms that BT is an effective, durable and safe treatment in severe asthmatics that have poorer asthma control at baseline compared to patients evaluated in previous clinical trials, such as AIR2," said Geoffrey Chupp, M.D., principal investigator and director, Yale Center for Asthma and Airways Disease, Yale University School of Medicine, New Haven, Connecticut. "The PAS2 study is the first large-scale, prospective study of BT performed in a post-market setting and validates the positive results from the AIR2 trial."

PAS2 is a prospective, open-label study that consecutively enrolled patients at 27 research centers in the United States and Canada. According to clinical guidelines from the European Respiratory Society and American Thoracic Society, 95 percent of PAS2 participants are considered severe asthmatics.[1] In comparison to AIR2 patients, PAS2 study participants were older, with more taking systemic steroids, had a higher Body Mass Index (BMI), and were on higher doses of inhaled steroids. In the 12 months prior to treatment with BT, PAS2 study participants were also more likely than AIR2 patients to have experienced both severe exacerbations, 74 versus 52 percent, and hospitalizations, 15 versus 4 percent.

"The results of the PAS2 study confirm that treatment with BT has an enormous and positive impact in every day clinical practice and may relieve some of the burden that adults with severe asthma face," said Art Butcher, senior vice president and president, Endoscopy, Boston Scientific. "We will continue to work to make sure that patients have access and coverage for this established, important treatment that has been shown to improve asthma-related quality of life."

Asthma affects more than 230 million people globally and approximately 10 percent of cases are considered severe.[2,3] The Alair™ System for BT is approved by the U.S. Food and Drug Administration (FDA) and has CE Mark for adult patients with severe asthma that is not well controlled with medication. It is the first non-pharmacologic, device-based treatment for severe, persistent asthma. Studies have shown that BT can reduce severe asthma attacks for at least 5 years.[4] Earlier this year, initial positive outcomes from the PAS2 full-study cohort were presented at the American Thoracic Society International Conference in Washington, D.C.

1. Chung, K F. "International ERS/ATS Guidelines On." *TASK FORCE REPORT*, American Thoracic Society ERS/ATS GUIDELINES ON SEVERE ASTHMA, 10 Apr. 2014, www.thoracic.org/statements/resources/allergy-asthma/Severe-Asthma-CPG-ERJ.pdf+.
2. WHO. Asthma Fact sheet N°307. April 2017. Available at:http://www.who.int/mediacentre/factsheets/fs307/en/index.html
3. "The Prevalence of Severe Refractory Asthma | AAAAI." The American Academy of Allergy, Asthma & Immunology. The Journal of Allergy and Clinical Immunology, Oct. 2014. Web. 05 May 2017. < https://www.aaaai.org/global/latest-research-summaries/New-Research-from-JACI-In-Practice/refractory-asthma >.
4. Wechsler M et al. J Allergy Clin Immunol. 2013 Dec;132(6):1295-302

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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, clinical trials, regulatory approvals and product performance and impact. 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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