Pulmonx to Market Zephyr® EBV Therapy for Patients with “Genetic” Emphysema

Company Receives Approval to Revise CE Labeling

August 29, 2012, Peseux, Switzerland– Pulmonx, an emerging leader in interventional pulmonology, announced today that its European notified body has granted CE approval for revised labeling of its Zephyr® Endobronchial Valve (EBV). The approval was based upon an independent review of two separate clinical data sets in which patients with hyperinflation associated with a genetic form of emphysema, Alpha-1 antitrypsin deficiency (AATD), were treated using the Pulmonx Zephyr EBV.

These new data sets reported improvements for FEV1 (forced expiratory volume in one second) and Residual Volume in AATD patients treated with Zephyr endobronchial valves, showing that patients with hyperinflation associated with emphysema can benefit from EBV treatment, independent of the underlying cause of the disease. No new procedural or device risks that may be associated with the treatment of AATD patients with the Pulmonx EBV were observed. The newly approved labeling provides a therapeutic option for physicians to use the Zephyr EBV to treat patients afflicted with hyperinflation associated with Alpha-1 Antitrypsin Deficiency.

“We have seen great success in the use of endobronchial valve therapy in selected patients suffering from Alpha-1 Antitrypsin Deficiency.” said Gunnar Hillerdal, Associate Professor of Lung Medicine, Karolinska University Hospital, Stockholm, Sweden. “The treatment options for these patients were previously very limited but their anatomy and the typical distribution of their disease can make them excellent candidates for EBV treatment. The recent label change should encourage pulmonologists to evaluate these patients for such treatment with confidence,” he continued.

About Alpha-1

Alpha-1 antitrypsin deficiency (AATD) is an inherited condition in which the body does not make enough of a protein that protects the lungs and liver from damage. Severe AATD can lead to emphysema or chronic obstructive pulmonary disease (COPD) in adult life.
About Pulmonx

Pulmonx, based in Redwood City, CA, and Peseux, Switzerland, is focused on developing and marketing minimally invasive medical devices and technologies for the diagnosis and treatment of pulmonary disorders. The Chartis System and Zephyr EBV are the first diagnostic and therapeutic solution to the problem of emphysema-induced hyperinflation. The Pulmonx Zephyr EBV and Chartis System are the subject of numerous peer-reviewed studies, and the Zephyr EBV has already been used to treat thousands of patients worldwide. www.pulmonx.com

The Zephyr EBV is an investigational device in the United States. Limited by U.S. law to investigational use. The Chartis System is for use/sale outside the United States only.

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