Pulmonx's Zephyr® Endobronchial Valve Demonstrates Statistically and Clinically Significant Results in a Prospective, Randomized Controlled Trial

September 09, 2014, Redwood City & Munich - The results of BeLieVeR-HIFi trial, the first double-blinded, randomized, controlled clinical trial to assess the impact of the Zephyr® Endobronchial Valve (EBV) for the treatment of emphysema, were presented today at the 2014 European Respiratory Society Conference in Munich by Nicholas S. Hopkinson, M.D., of The Royal Brompton & Harefield NHS Foundation Trust in London.

In the study, the third randomized clinical trial of the Zephyr device, patients with emphysema receiving the valves demonstrated statistically and clinically significant improvements in lung function, gas trapping and gas exchange, as well as exercise capacity measured on a cycle ergometer. The mean improvement in FEV_1, a measure of pulmonary function, was 25% in treated patients. In addition, the procedure showed an acceptable safety profile, with clinically significant improvements in walking distance and quality of life.

"Many patients with emphysema remain very disabled because even optimal medical therapy is of limited benefit. However, this study shows clearly that in appropriately selected individuals with emphysema, endobronchial valves offer a real prospect for improving lung function, exercise capacity, and quality of life," said Dr. Hopkinson, who served as a principal investigator for the trial.

The Zephyr® EBV helps reduce the amount of trapped air in the treated lung, thereby improving the patient's breathing mechanics and ability to exercise. Previous studies of the device demonstrate sustained improvement,[1,2,3] and a survival benefit[4,5] was later observed in patients without cross-communication between the different regions of their lungs. The BeLieVeR-HIFi study deliberately targeted only this specific type of patient to prospectively confirm this finding.

"The results of this study add to the growing body of evidence for the Zephyr valve, which has now been used to treat approximately 8,500 patients with emphysema around the world," said Oern Stuge, M.D., Interim CEO, Pulmonx. *"We look forward to continued validation of the effectiveness of the therapy in appropriately selected and treated patients with the conclusion of a number of ongoing studies."*

The Zephyr® EBV was the first device study funded in part by the Efficacy and Mechanism Evaluation program of the MRC (Medical Research Council) and the NIHR (National Institute for Health Research) in the U.K.

The Zephyr® EBV is commercially available in Europe as well as other international markets and is an investigational device in the United States.

About Zephyr®

The Zephyr® Endobronchial Valve is a minimally invasive device intended to treat patients with emphysema. Emphysema patients suffer from hyperinflation, an increase in volume of the diseased portions of their lungs, which then compresses the healthier areas. The Zephyr® EBV therapy involves bronchoscopic placement of one-way valves designed to reduce the hyperinflation in the diseased portion of the lungs, thereby improving the ability of the healthier portions of the lungs to function. The Zephyr® EBV received the CE Mark in 2003. Since becoming commercially available in Europe and select countries worldwide, the company estimates that it has been used to treat over 8,500 patients.

About Chartis

The Pulmonx Chartis Pulmonary Assessment System provides pulmonologists with lobe-specific information about a patient's lung, enabling physicians to plan valve treatments to account for anatomical variations in the lungs of individual patients which impact the effectiveness of the valves. The addition of the Pulmonx Chartis assessment now ensures that a very high percent of treated patients will experience benefit from EBV treatment. The Chartis Pulmonary Assessment System and accessories are FDA 510(K) cleared devices.

About Pulmonx

Pulmonx, based in Redwood City, California, and Neuchâtel, Switzerland, is focused on developing and marketing minimally invasive medical devices and technologies for the diagnosis and treatment of pulmonary disorders. **www.pulmonx.com**

The Zephyr® EBV is an investigational device in the United States. Limited by U.S. law to investigational use.

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Pulmonx
Steve Ricottone
Neuchâtel, Switzerland
Phone: +41 79 101 20 65
E-Mail: sricottone@pulmonx.com

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