Pulmonx Gains Regulatory Approval for Expanded Labeling for Emphysema Treatment

New labeling clears the way for the treatment of many more patients

January 10, 2012, Neuchâtel, Switzerland – Pulmonx SARL today announced that its European notified body has granted CE approval for expanded labeling of its Zephyr® endobronchial valve (EBV). The approval was based upon an independent review of clinical data from numerous studies including the recently completed Chartis multi-center study[1] and the European VENT study (a randomized multi-center European trial of Zephyr EBV therapy)[2]. The Chartis Multi-Center Study data was presented at the European Respiratory Society's 2011 Congress in September and the data from the European VENT study was accepted in December 2011 for publication in the European Respiratory Journal.

These new data sets confirm that Zephyr EBV treatment is a safe and efficacious approach to managing the crippling hyperinflation that occurs in emphysema patients regardless of the degree of disease heterogeneity that is observed on a patient's CT examination. Earlier studies had established the safety and efficacy of Zephyr EBV therapy in patients with a relatively high disease heterogeneity score on CT examination. The new data and the newly approved labeling clear the way for physicians to use Zephyr EBV therapy to treat a much broader range of the population of patients afflicted with emphysema.

"The most recent data clearly confirms that EBV therapy should not be restricted to only those patients whose emphysema is scored as highly heterogeneous on CT examination and that it can be safely used to treat hyperinflation in a broad range of emphysema patients," said Professor Felix Herth, MD, PhD., FCCP, Chairman and Head of Pneumology and Respiratory Care at Thoraxklinik, University of Heidelberg, Germany. "This reinforces my belief that Chartis and EBV treatment should become a standard-of-care in the management of emphysema."

****

---

1 Gompelmann D et al Use of Chartis® System to Optimize Subject Selection for Endobronchial Lung Volume Reduction (ELVR) in Subjects with Heterogeneous Emphysema. Oral presentation ERS Amsterdam 2011

2 Herth FJH et al Efficacy Predictors of Lung Volume Reduction with Zephyr Valves in a European Cohort Eur Respir J Accepted for publication Dec 2011

About Emphysema

Emphysema is a form of chronic obstructive pulmonary disease (COPD) that occurs when the air sacs in the lungs are gradually destroyed, leading to shortness of breath even while at rest. Globally over 30 million patients have been diagnosed with emphysema. COPD is a major cause of disability and a major public health problem. The World Health Organization ranks it as the fourth leading cause of death today and it is expected to become the third leading cause of death worldwide by 2030s. Most patients suffering from emphysema currently have few options for treatment. Emphysema is a major economic problem and a burden on the global healthcare system, due to millions of work days missed, expensive and minimally effective therapies and frequent hospitalizations related to the disease.

About The Chartis Multi-Center Study

This European study enrolled patients at sites in Germany, Netherlands, and Sweden between May 2010 and March 2011. A broad range of severe emphysema patients were allowed to enroll. Final data was completed for 80 patients, showing a median volume reduction in the treated lobe of 72% in predicted responders vs. 4% in predicted non-responders. The Chartis® system accurately predicted response in 3 out of 4 patients. Predicted responders experienced clinically significant improvements in all of the study endpoints, measured 30 days after treatment while predicted non-responders experienced little or no benefit on average. 39% of these predicted responders had a heterogeneity score which was below the 15% threshold which has traditionally been used as the criteria to define heterogeneous emphysema.

About the European VENT Multi-Center Randomized Trial

In the European cohort of the VENT study, 111 patients were randomized to EBV treatment and 60 to best medical care. Patients were followed up for 12 months. In the high responder group of EBV treated patients, 45% had a heterogeneity score below the 15% threshold and thus would not be considered as having heterogeneous emphysema. Clinically significant improvements were observed in this group of patients and these improvements were sustained over 12 months.

About the Chartis and Zephyr Technologies

Emphysema patients suffer from hyperinflation--an increase in volume of the diseased portions of their lungs which then compresses the healthier areas. This results in breathlessness and costly disability. Many patients cannot carry out even the most basic activities of everyday living, and may require supplemental oxygen. Zephyr® valves can reduce volume in the diseased portion of the lungs thereby improving the ability of the healthier portions of the lungs to function, and relieving the patient's symptoms, as well as allowing patients to increase their activity levels, promoting better overall health.

Previously published studies on the Zephyr endobronchial valve have confirmed the safety of the treatment, as well as its effectiveness in a subset of emphysema patients. The challenge in applying the therapy to a broad population of emphysema patients had been the ability of physicians to plan valve treatments to account for anatomical variations in the lungs of individual patients which impact the effectiveness of the valves. The Pulmonx Chartis System provides new information about specific areas

of the patient's lung, enabling more informed treatment planning. The addition of the Chartis assessment now ensures that a significant percent of treated patients will experience benefit from EBV treatment.

About Pulmonx

Pulmonx, based in Neuchâtel, Switzerland and Redwood City, CA, is focused on developing and marketing minimally-invasive medical devices and technologies for the diagnosis and treatment of pulmonary disorders. The company established its European headquarters in Switzerland in 2010 in order to better serve the European and global marketplace. Pulmonx is adding employees to its Neuchâtel offices and elsewhere in Europe as its business continues to grow. The Chartis System and Zephyr EBV is the first effective diagnostic and therapeutic solution to the problem of emphysema-induced hyperinflation. www.pulmonx.com.

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.

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.

Contact:

Pulmonx
Michael A. Baker, +41 32 557 5800 / +1 650-216-0150
President and Chief Executive Officer
mbaker@pulmonx.com