New Data From Two Multi-Center Randomized Clinical Trials Demonstrate That Zephyr® Endobronchial Valves Deliver Benefit to Both Heterogeneous and Homoegenous Emphysema Patients Without Collateral Ventilation

May 23, 2017

Washington DC and Redwood City, Calif. – May 23, 2017 – Pulmonx, Inc. today announced the results of two multi-center, randomized clinical trials showing clinically meaningful improvements in lung function after treatment with the Zephyr® Endobronchial Valve (EBV) in emphysema patients without collateral ventilation. Six-month data from both the TRANSFORM and IMPACT trials, presented this week at the American Thoracic Society international conference, demonstrate that Zephyr valves provide positive benefits in these patients with either homogeneous or heterogeneous distribution of emphysema.

Zephyr Endobronchial Valves are tiny, minimally-invasive, one-way valves placed via a flexible bronchoscope in airways of the lungs to occlude diseased regions and reduce lung hyperinflation. As a result, the remaining healthier regions can function more efficiently, enabling better breathing and an improved quality of life for patients.

In the clinical trials, patients were selected based on the absence of collateral ventilation (airflow between regions of the lung that bypasses normal airways), which was assessed in the trials using the Chartis Pulmonary Assessment System from Pulmonx. The effectiveness of endobronchial valves is dependent on selection of an area of the lung without collateral ventilation for treatment.

The TRANSFORM study, a multi-center, prospective, randomized, controlled trial, evaluated 97 patients with heterogeneous (more focally-distributed) emphysema at **17 centers in six countries**. Patients were randomized 2:1 to Zephyr valve treatment versus standard of care. The authors concluded that Zephyr valve treatment in heterogeneous emphysema patients without collateral ventilation confers clinically and statistically significant sustained benefits, with improvements in lung function, exercise capacity and quality of life.

At six months, 56.3 percent of patients treated with Zephyr valves achieved a 12 percent or greater improvement in lung function (FEV_1) from baseline, when compared to 3.2 percent of patients in the control group. **The lung function (FEV_1)** in the Zephyr valve-treated group was **on average 29.3 percent higher** than the control group. Improvements of a similar magnitude were observed between groups in exercise capacity (measured by **Six-Minute Walk Distance**, or 6MWD), with Zephyr valve-treated patients improving upon the control group by **78.7 meters**. Finally, the quality of life of Zephyr valve treated patients improved by

6.5 points over control in the St. Georges Respiratory Questionnaire (SGRQ) score.

"The magnitude of benefits to patients in this pan-European trial are dramatic and reinforce results published from prior single center studies," said Dr. Samuel Kemp, principal investigator and respiratory physician at the Royal Brompton Hospital, London, UK. "Using Chartis for patient selection enabled us to accurately identify patients without collateral ventilation, which is a key predictor for good outcomes with this device."

The IMPACT study enrolled 93 patients with severe homogeneous (more diffusely-distributed) emphysema who were randomized 1:1 to Zephyr® valve treatment versus medical management. Consistent with the previously published three-month data, the improvements remained statistically and clinically significant at **six months** with Zephyr valve treated patients experiencing **improvements over control for FEV_1 of 16.3 percent** ($p<0.001$), an **increase in 6MWD of 28.3 meters** ($p=0.016$), and an improvement in the quality of life based on a decrease in the **SGRQ score of – 7.5 points** ($p<0.001$).

The most common side effect of the Zephyr valves in both studies was **pneumothorax** (20 to 26 percent in the treated group) and **chronic obstructive pulmonary disease exacerbations** (11 to 28 percent versus 6 to 18 percent in the control group) in the immediate post-procedure period. Both were addressed with standard medical management.

Two prior randomized controlled trials of the Zephyr valve in patients without collateral ventilation (the STELVIO and BeLieVeR-HIFi trials) also support the ability of Zephyr valves to significantly improve lung function, exercise tolerance and quality of life.1,2 Additional published clinical data demonstrate sustained patient benefits out to five years3 and suggest potential survival benefits at five and 10 years post-treatment,4,5 indicating a possible slowing in disease progression.

"For patients with severe emphysema, there were previously few therapeutic options," said Pulmonx Chief Executive Officer Glen French. "Now, we have consistent data from four randomized studies showing that, regardless of disease heterogeneity, when patients are selected for the absence of collateral ventilation, they can gain substantial benefits in quality of life, exercise capacity and lung function with Zephyr valves."

Over the past 10 years, approximately 50,000 Zephyr EBVs have been implanted globally in more than 12,000 patients. To view a video of the Zephyr EBV procedure, click here.

About Pulmonx

Based in Redwood City, California, and Neuchâtel, Switzerland, Pulmonx is an interventional pulmonology company focused on developing life-changing, cost-effective technologies that improve the lives of patients suffering from lung disease worldwide. For more information, visit www.pulmonx.com.

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

References:

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GLO-EN-642-v1