Pulmonx Announces Presentation of Clinical Data from the AeriSeal® CONVERT Trial and 5-Year Follow-up Data from the LIBERATE Study at the European Respiratory Society Congress 2024

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CONVERT trial data demonstrate AeriSeal® System is safe and effective with 77.6% of patients converted from CV+ to CV-

5-year durability data from LIBERATE study demonstrate positive, durable benefits to patients treated with Zephyr® Valves

REDWOOD CITY, Calif. & VIENNA, Sept. 09, 2024 (GLOBE NEWSWIRE) -- Pulmonx Corporation (Nasdaq: LUNG) ("Pulmonx"), a global leader in minimally invasive treatments for severe lung disease, announced the presentation of clinical data from the AeriSeal® CONVERT trial and 5-year follow-up data from the LIBERATE study at the European Respiratory Society (ERS) Congress in Vienna, Austria.

Presented data from the CONVERT trial demonstrated that treatment with the AeriSeal System is safe and effective in occluding small airways and/or collateral air channels allowing patients with collateral ventilation to undergo and benefit from treatment with Zephyr® Endobronchial Valves. Presented 5-year follow-up data from the LIBERATE study showed patients treated with Zephyr Valves experience durable improvements in lung function out to at least 5 years.

AeriSeal CONVERT Trial
Professor Kaid Darwiche, Head, Department of Interventional Pneumology, Ruhrlandklinik, Essen, Germany gave a presentation titled, *Zephyr Valve benefits previously ineligible patients after blocking of collateral channels with AeriSeal: CONVERT Trial.* The reported data from the full 101-patient cohort in the CONVERT trial demonstrated 77.6% of patients with collateral ventilation (CV+) treated with AeriSeal successfully experienced conversion. Furthermore, following conversion, patients treated with Zephyr Valves experienced clinically meaningful improvements over the baseline with:

- Improved lung function of 80mL or 10.2% over the baseline as measured by Forced Expiratory Volume in 1 second (FEV1)
- Improvement of 6.3 points in quality of life measured by the St. George's Respiratory Questionnaire
- Mean treated lobe volume reduction (TLVR) of greater than one liter at 45 days
- 89% of CV- converted patients achieved a TLVR equal to or greater than 350mL, the minimal clinical important difference, at 6-months following valve implantation

These findings show that patients with collateral ventilation can successfully undergo bronchoscopic lung volume reduction (BLVR) with Zephyr Valves following closure of the fissure gap with the AeriSeal System.

"Treatment options beyond medical management for patients with severe emphysema remain inadequate. Zephyr Valves, a minimally invasive treatment option proven to improve patients' ability to breathe is not effective when collateral ventilation is present," explains Professor Darwiche. "We are excited about the opportunity the AeriSeal System presents for patients who are collateral ventilation positive to convert to collateral ventilation negative status and become eligible for Zephyr Valves."

"Pulmonx is meeting our commitment to develop and test innovative technologies that help patients with severe lung disease have a better quality of life," said Steve Williamson, President and Chief Executive Officer of Pulmonx. "We are extremely encouraged by these results and look forward to progressing further with our US IDE trial, CONVERT II, which is expected to enroll through approximately the beginning of 2026."

5-Year Follow-Up from LIBERATE Study
Professor Gerard Criner, Chair of Thoracic Medicine and Surgery at Temple University in Philadelphia, PA, gave a presentation at the ERS Congress titled, *Five-Year Durability of Zephyr Valves in Patients with Severe Emphysema.* The 5-year follow-up data for the Zephyr Valve treated patients from the LIBERATE study demonstrate durable improvements out to at least 5 years. More specifically, the data shows durable long-term benefits over the baseline with:

- Annual improvements in lung function measured by FEV1 ranging from 109 mL in Year 1 to 79 mL at Year 5, with an acceptable safety profile
- FEV1 improvement over the baseline through year 5 is considered an advantage over maximal medical treatment alone given the known decline in lung function over time
- Similar or lower incidence of respiratory adverse events or serious adverse advents (SAEs) through Year 2 to Year 5 compared to Year 1 post-procedure
- No new types or increase in frequency of respiratory SAEs compared to prior years

- 38% mortality over the 5-year period, below the mortality of 49% in historical medically managed control patients[1]

Also, at the ERS Congress, Dr. Frank Sciurba, Professor of Medicine and Education and Director, Emphysema/ COPD Research Center at the University of Pittsburgh School of Medicine, Pittsburgh, PA, gave a presentation titled, *Lobar Volume Reduction of ≥50% with Zephyr Valves Correlates with Significant Reduction in Longer-term Rate of Severe COPD Exacerbations.* The post-hoc analysis of the LIBERATE study data demonstrate that a TLVR of 50% or above, following treatment with Zephyr Valves, is correlated with significantly fewer severe COPD exacerbations requiring hospitalization compared to the medically managed control group over the long-term.

Professor Criner noted that, “The data demonstrate the durability of treatment with Zephyr Valves out to at least 5 years despite the progressive nature of lung disease for a large population of COPD/emphysema patients with very few alternative treatment options that do not involve major surgery.”

“We are pleased with the durability data shown in the 5-year follow-up results from the LIBERATE study as our ever-growing body of evidence further validates the clinical benefits of Zephyr Valves for patients with severe emphysema and COPD,” said Steve Williamson, President and Chief Executive Officer of Pulmonx.

About the CONVERT Trial
CONVERT is a prospective, open-label, multi-center, international, single-arm trial conducted at up to 20 investigational sites. The trial enrolled 101 subjects with severe emphysema, and collateral ventilation in the target lobe. The 101 enrolled subjects included both heterogeneous and homogeneous emphysema subjects reflecting current clinical practice. This protocol is designed to evaluate the utility of the AeriSeal System, which uses a synthetic polymer foam to occlude, or close, collateral air channels in a target lung lobe and convert the target lung lobe to having little to no collateral ventilation (CV-). Converted patients then underwent Bronchoscopic Lung Volume Reduction with Zephyr Endobronchial Valves. Zephyr Valves are not effective if collateral ventilation (CV+) is present but once the treated lobe is converted from CV+ to CV-, patients can be treated with Zephyr Valves which has been shown to improve lung function, quality of life, and exercise capacity for patients with severe COPD/emphysema.[2] See https://clinicaltrials.gov/ct2/show/NCT04559464 for more details on the CONVERT trial.

The AeriSeal System has received a “Breakthrough Device” designation by the Food and Drug Administration. It is not approved by the FDA or approved for commercial sale in the United States.

About the CONVERT II Pivotal Trial
The CONVERT II Pivotal Trial is designed to evaluate the safety and effectiveness of the AeriSeal System in limiting collateral ventilation in severe COPD and emphysema patients. The trial will enroll approximately 200 patients in and outside the United States. Patients who experience conversion following the AeriSeal System treatment will then be treated with Zephyr Valves per current standard of care for lung volume reduction. Procedural success, defined as lung volume reduction, and other clinical parameters will be evaluated at six months post-valve treatment and will be used to support the company’s premarket approval application.

About Zephyr Valves
The Zephyr Endobronchial Valve is a minimally invasive treatment option for severe COPD/emphysema. Zephyr Valves are placed via bronchoscopy to block off a diseased portion of the lung to prevent air from getting trapped and reduce hyperinflation, which allows the healthier lung tissue to expand and take in more air. This results in patients being able to breathe easier, be less short of breath, and have an improvement in their quality of life.[2] National and global treatment guidelines for COPD include Endobronchial Valves like Zephyr Valves as a recommended treatment option for patients with severe COPD/emphysema, with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) giving valves an ‘Evidence A’ rating. More than 40,000 patients have been treated with Zephyr Valves worldwide.

About Pulmonx Corporation
Pulmonx Corporation (Nasdaq: LUNG) is a global leader in minimally invasive treatments for chronic obstructive pulmonary disease (COPD). Pulmonx’s Zephyr® Endobronchial Valves, Chartis® Pulmonary Assessment System and StratX® Lung Analysis Platform are designed to assess and treat patients with severe emphysema/COPD who despite medical management are still profoundly symptomatic. Pulmonx received FDA pre-market approval to commercialize Zephyr Valves following its designation as a “breakthrough device.” The Zephyr Valve is commercially available in more than 25 countries, is included in global treatment guidelines and is widely considered a standard of care treatment option for improving breathing, activity and quality of life in patients with severe emphysema. For more information on the Zephyr Valves and the company, please visit www.Pulmonx.com.

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Forward Looking Statements
This release contains forward-looking statements within the meaning of Sections 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We may, in some cases, use terms such as “look forward,” “confident,” “promises,” “predicts,” “believe,” “potential,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements and include, without limitation, statements about Pulmonx’s ability to treat a greater number of patients and deliver significant benefits to patients. Forward-looking statements should not be read as a guarantee of future performance or results and may not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. These forward-looking statements are based on Pulmonx’s current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation those related to the safety, efficacy and patient and physician adoption of the company’s products, the ability to fully enroll and the final results and outcomes of clinical trials and studies involving the Company’s products, the ability to obtain and maintain reimbursement codes for its products, and the company’s ability to procure and maintain required regulatory approvals for its products. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in Pulmonx’s filings with the Securities and Exchange Commission (SEC), including the Company’s Quarterly Report on Form 10-Q filed with the SEC on August 2, 2024, available at www.sec.gov. Pulmonx does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained here/in.

References
[1] Naunheim KS et al. Ann Thorac Surg 2006; 82: 431– 443.

[2] Criner G et al. Am J Respir Crit Care Med. 2018; 198 (9): 1151–1164.

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