Pulmonx Announces Treatment of the First Patient with the AeriSeal® System in CONVERT II Pivotal Trial

February 26, 2024

AeriSeal System Shows Promise in Limiting Collateral Ventilation, Potentially Enabling a Greater Number of Severe COPD/Emphysema Patients to Benefit from Treatment with Zephyr® Valves, a Minimally Invasive Treatment Option

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Feb. 26, 2024-- Pulmonx Corporation (Nasdaq: LUNG) ("Pulmonx" or the "Company"), a global leader in minimally invasive treatments for chronic obstructive pulmonary disease (COPD), today announced the treatment of the first patient in the CONVERT II Pivotal Trial, a multicenter, international study evaluating the safety and effectiveness of the AeriSeal® System in limiting collateral ventilation in severe COPD/emphysema patients. Collateral ventilation is caused by openings in the lung fissures, or walls between the lung lobes. The AeriSeal System is designed to occlude these naturally occurring openings in a lobe targeted for bronchoscopic lung volume reduction (BLVR) and block collateral ventilation. Successful treatment with the AeriSeal System is followed by treatment with commercially available Zephyr® Valves. Pulmonx received a staged IDE approval by the Food and Drug Administration (FDA) to commence the CONVERT II Pivotal Trial for the AeriSeal System in late 2023.

The goal of the CONVERT II Pivotal Trial is to establish the safety and effectiveness of using the AeriSeal System to target and treat the fissural defects that allow collateral ventilation between lung lobes which preclude some severe COPD/emphysema patients from benefiting from BLVR with Zephyr Valves. Severe COPD/emphysema patients with collateral ventilation confirmed with Pulmonx's proprietary Chartis ® Pulmonary Assessment System (Chartis) undergo the AeriSeal System treatment. For those patients who experience conversion (as assessed with the Chartis System 45 days later), Zephyr Valves are implanted per current standard of care for lung volume reduction. Procedural success (lung volume reduction) and other clinical parameters including lung function, quality of life and exercise capacity, will be evaluated at 6 months post-valve treatment. The 6-month results will be used to support a Pre-Market Approval (PMA) application. Up to 200 patients will be enrolled at up to 30 sites in the US, Australia, and Europe (ClinicalTrials.gov Identifier: NCT06035120). The study will complement the positive experience that the Company has already gained with the CONVERT Trial (ClinicalTrials.gov Identifier: NCT04559464)[1].

Endobronchial Valves are small, one-way valves used to reduce hyperinflation of the lungs, the primary cause of breathlessness in patients with severe COPD/emphysema. If collateral ventilation is present, the treated lobe will not deflate, and the valves are not effective. AeriSeal Foam is designed to block gaps in lung fissures so that patients may then benefit from treatment with endobronchial valves like the Zephyr Valve. Zephyr Valves have been clinically proven to improve breathing, lung function, and quality of life for patients with advanced disease.[2]

"This is very promising news for patients with severe COPD/emphysema because as the diseases progresses, medications alone often do not control symptoms sufficiently. We know Zephyr Valves can provide durable improvements in lung function, breathing, and quality of life, but for patients with incomplete fissures the treatment does not work effectively," explains Dr. Michela Bezzi, Director Interventional Pulmonology - ASST Spedali Civili, University Hospital, Brescia, Italy. "Having a technology to seal openings in fissures means we can improve the lives of many more patients using minimally invasive procedures."

"Pulmonx remains at the forefront in developing and testing new medical technologies to help patients with severe lung disease breathe easier and have better quality of life," stated Glen French, President and Chief Executive Officer of Pulmonx. "We hope the CONVERT II Trial will move us closer to the goal of helping patients with collateral ventilation to also receive benefit from our Zephyr Valves."

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 study 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 the Zephyr Valve Treatment

The Zephyr Valve is a minimally invasive treatment option for severe COPD/emphysema, a chronic, progressive, and irreversible lung disease characterized by the destruction of lung tissue. The loss of the lung's natural elasticity and the collapse of airways cause air to become trapped in the lung. This makes breathing inefficient, and patients are always short of breath, making the most nominal physical activities difficult. Placed via bronchoscopy, the valves 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, with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) giving valves an 'Evidence A' rating.

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 Valve, 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 the Zephyr Valve 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.

Forward Looking Statements

This release contains forward-looking statements within the meaning of Sections 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect our strategy, operations, financial performance, or clinical progress and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements should not be read as a guarantee of future performance or results. 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 AeriSeal System and the Company's other products, the ultimate outcomes, completion, or success of the CONVERT II Pivotal Trial, the ability to obtain and maintain reimbursement codes for its products, and the Company's ability to procure and maintain required regulatory approvals for the AeriSeal System and its other 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 November 3, 2023, 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 herein.

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[1] *Eur Respir J* 2022; 60: Suppl. 66, 1231.

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

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