Pulmonx Receives Japanese MHLW Approval of Zephyr Endobronchial Valve for the Treatment of Severe COPD/Emphysema

November 30, 2022

Approval of First Minimally Invasive Treatment Option in Japan that Helps Patients with Advanced Disease Breathe Easier and Have a Better Quality of Life

REDWOOD CITY, Calif. & TOKYO--(BUSINESS WIRE)--Nov. 30, 2022-- Pulmonx Corporation (Nasdaq: LUNG) ("Pulmonx"), a global leader in minimally invasive treatments for severe lung disease, announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved the Zephyr® Endobronchial Valve for treating severe COPD/emphysema patients following a positive recommendation by Pharmaceuticals and Medical Devices Agency (PMDA). The Zephyr Valve is a minimally invasive treatment option that can deliver significant benefits to patients including improvements in lung function, exercise capacity, and quality of life.[1] Placed by bronchoscopy, with no cutting or incision, the valves are for patients who remain symptomatic despite optimal management including medications, pulmonary rehabilitation, and supplemental oxygen. Pulmonx intends to collaborate with the Japanese MHLW to gain reimbursement prior to commercialization in Japan to ensure broader access to its innovative and clinically proven treatment.

"The Zephyr Valve is a breakthrough technology because it is the first bronchoscopic procedure option that can provide significant improvements to patients with no improvement in their symptoms despite optimal medical therapy," stated Prof. Masamichi Mineshita, St. Marianna University School of Medicine, Department of Respiratory Medicine, Kawasaki, Japan. "Many patients with advanced disease continue to struggle to breathe, making even simple daily tasks difficult. Having a treatment that can help patients breathe easier and live a better quality of life, without surgical intervention, will be a major step forward in COPD care in Japan."

Over 600,000 Japanese patients suffer from severe COPD, including approximately 100,000 patients with severe disease where hyperinflation causes them to remain symptomatic despite adhering to their medications, doing pulmonary rehabilitation, and using supplemental oxygen.[2] Hyperinflation, in which air becomes trapped in the lungs and prevents new air from coming in, causes severe shortness of breath. The inability to get enough air and proper gas exchange in the lungs often prevents these patients from doing simple daily activities such as bathing, getting dressed, performing household chores and walking, without stopping to catch their breath. Until now, the only other options for these patients were invasive treatments such as lung volume reduction surgery or lung transplantation.

The one-way Zephyr Valves are placed in a selected lobe of the lung (generally the most diseased lobe and with little to no collateral ventilation) during a bronchoscopic procedure to occlude the target lobe and reduce hyperinflation. This relieves pressure off the diaphragm and allows the healthier parts of the lungs to expand and function more effectively, thereby decreasing shortness of breath and making breathing easier.[1]

"We are excited about this approval and the opportunity to enable the Japanese medical community to bring a much-needed treatment option to patients with severe COPD/emphysema," stated Glendon French, President and Chief Executive Officer of Pulmonx. "Japan is the second largest healthcare market in the world and represents a valuable opportunity to bring our innovative treatment to a large group of patients who have had few options once medical management alone fails to control their disease."

The approval is based on a thorough review by the PMDA of the positive clinical data from the pivotal LIBERATE Study[1] that enrolled patients with heterogenous emphysema distribution and the IMPACT Study[3] that included patients with homogeneous emphysema distribution. Both studies were published in the *American Journal of Respiratory and Critical Care Medicine* and showed that patients treated with Zephyr Valves had a statistically significant and clinically meaningful improvement in lung function, exercise capacity, and quality of life compared to patients who received medical management alone.

About Zephyr Valves

The Zephyr 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.[1] Patients most likely to benefit from Zephyr Valve treatment can be identified with assessment tools also offered by Pulmonx. Physicians use the Pulmonx Chartis® Pulmonary Assessment System to help identify potential responders to Zephyr Valve treatment.

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. More than 25,000 patients have been treated with the Zephyr Valve worldwide.

About Pulmonx Corporation

Pulmonx Corporation (NASDAQ: LUNG) is a global leader in minimally invasive treatments for severe lung disease. Pulmonx's Zephyr ® Endobronchial Valve and Chartis® Pulmonary Assessment System are designed to assess and treat patients with severe emphysema/COPD who, despite medical management, are still profoundly symptomatic. Pulmonx received FDA premarket approval to commercialize the Zephyr Valve following its designation as a "breakthrough device." The Zephyr Valve is commercially available in more than 25 countries, with over 100,000 valves used to treat more than 25,000 patients. For more information on the Zephyr Valves please visit https://uspatients.pulmonx.com/. For more information

on 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 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 designation of our products and therapies as a standard of care, the final results and outcomes of clinical trials and studies involving the Company’s products, the ability to obtain and maintain adequate reimbursement 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 November 8, 2022, 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.

1. Criner G et al. Am J Respir Crit Care Med. 2018; 198 (9): 1151–1164.
2. Tanabe N et. al. J. Thorac Dis. 2021 Jun; 13(6): 3878–3887; Soriano JB et al. Lancet Respir Med. 2015 Jun;3(6):443-50; Welling JBA et al. Int J Chron Obstruct Pulmon Dis. 2020; 15: 1179–1180. See also Statistics Bureau of Japan (https://www.stat.go.jp/english/data/jinsui/tsuki/index.html) (accessed on 10-25-22)
3. Valipour A. et al. Amer J Respir Crit Care Med. 2016; 194(9):1073–1082.

Pulmonx®, Chartis®, and Zephyr® are registered trademarks of Pulmonx Corporation.

View source version on businesswire.com: https://www.businesswire.com/news/home/20221027005705/en/

Japan Media Contact:
Russel Haskin / Yoshitaka Sego
PulmonxJapan@pulmonx.com

US Media Contact:
Meghan Oreste
617-823-1441
moreste@Pulmonx.com

Investor Contact:
Brian Johnston
Gilmartin Group
investors@pulmonx.com

Source: Pulmonx Corporation