



PneumRx, Inc.'s RePneu Coil Becoming Therapy of Choice for Patients with Severe Emphysema

MOUNTAIN VIEW, Calif., Sept. 26, 2013 /PRNewswire/ -- PneumRx, Inc., a leader in interventional pulmonology, announced that over 1500 procedures have been performed using the RePneu Lung Volume Reduction Coil (LVRC) System for patients with severe emphysema.

The RePneu LVRC is a minimally invasive device intended to improve lung function, exercise capacity and quality of life in emphysema patients by bronchoscopically implanting Nitinol coils into the lung to compress diseased tissue, restore elastic recoil, and re-tension the airway network. This treatment is a minimally invasive treatment that is effective for a broad range of emphysema patients.

The RePneu LVRC's impressive market adoption is evidenced by the fact that over 1500 RePneu LVRC treatments have been performed, involving over 15,000 Coils, even though the LVRC has been commercially available for just over 2 years. In addition to being commercially available in Germany, Italy, Switzerland and Turkey, the RePneu LVRC was selected by the French Ministry of Health for, and is currently undergoing, a multi-center cost-effectiveness study in France (STIC), supported by the French Ministry of Health. Over 75 subjects have been enrolled in the French study, the REVOLENS, since March 2013, and enrollment is expected to be completed, ahead of schedule, before the end of the year.

The RePneu LVRC is rapidly becoming the therapy of choice for emphysema patients in European markets because of its ability to treat a broad range of emphysema patients without requiring any complex diagnostic evaluation. The RePneu Coil does not block airways, prevent distal access, or destroy lung tissue, but instead provides a simple mechanical solution designed both to treat the key physiologic effects of emphysema and to overcome the key challenges of emphysema treatment. As evidenced by the data presented at the recent European Respiratory Society (ERS) meeting in Barcelona, Spain, the RePneu Coil is unique in its ability to treat patients with both heterogeneous and homogeneous emphysema, in both upper and lower lobes, in patients with Residual Volume of 175% predicted and above. In addition, the RePneu LVRC works independently of collateral ventilation, and is performed in a gentle, well-tolerated procedure with a rapid recovery period.

The RePneu Coil is also used extensively in the Netherlands and the UK. Dr. Dirk-Jan Slebos, of the University Medical Center, Groningen, the Netherlands, has implanted over 1,000 Coils in emphysema patients and is expected to treat 40 subjects this year in the 315-subject, multicenter pivotal study, RENEW, the results of which will be submitted for commercial approval of the RePneu LVRC in the US. Also participating in the RENEW Study is Dr. Pallav Shah of the Royal Brompton and Hareford National Hospital Trust and the Chelsea and Westminster National Hospital Trust in London, U.K. Dr. Shah previously participated in a multi-center, randomized, controlled study of the LVRC in the UK (the RESET Study), the results of which were published this year in The Lancet Respiratory. Among the findings in that study, subjects treated with the RePneu LVRC showed statistically and clinically significant improvements in exercise capacity (6MWT), lung function (FEV1, Residual Volume), and quality of life (SGRQ) as compared to subjects who received best medical care, but no LVRC procedures. In particular, subjects who received treatment with the RePneu LVRC improved an average of over 63 meters in 6MWT as compared to subjects who received best medical care.

This rapid adoption of the RePneu LVRC technology is generating a growing body of data that shows that the RePneu Coil consistently provides safe and effective treatment to a broad range of emphysema patients. Much of this data was presented earlier this month at the ERS. Seven interventional pulmonologists from Germany, France, Italy, the UK and the Netherlands presented study data demonstrating the safety and effectiveness of the RePneu LVRC. In addition, a symposium on the RePneu LVRC technology, featuring presentations by interventional pulmonologists from Germany, France, the Netherlands and Switzerland, generated a significant amount of interest. For more information about the RePneu LVRC and the RENEW study, visit

www.pneumrx.com or

<http://www.clinicaltrials.gov/ct2/show/NCT01608490?term=RENEW&rank=1>

About Advanced Emphysema

More than 15 million people worldwide suffer from advanced emphysema, a chronic, debilitating disease most commonly brought on by years of smoking. Emphysema causes irreversible damage to delicate lung tissue, leading to shortness of breath and even feelings of suffocation that result in reduced quality of life. Emphysema is medically characterized by reduced lung function, increased lung volume and loss of the lung's natural elastic properties, which makes breathing very difficult.

Emphysema is medically characterized by reduced lung function and increased lung volume, which makes breathing very difficult. As the disease progresses and the lung's natural elastic properties are destroyed, excess air is trapped in the lungs, making it difficult for the person to exhale. This process is known as hyperinflation and is responsible for the feeling of being "short of breath." The RePneu LVRC works by compressing the hyperinflated lung tissue to reduce volume, while helping to restore the lung's natural elastic recoil. The LVRC also helps hold open the lung's airways, preventing airway collapse that causes air trapping and hyperinflation. Implanting the

LVRC involves a minimally invasive, non-surgical procedure, and most patients are able to return home the following day.

As the disease progresses and lung tissue is destroyed, excess air is trapped in the lungs making it difficult for the person to exhale. This process is known as hyperinflation and responsible for the feeling of being "short of breath." Patients with severe emphysema experience shortness of breath nearly all the time, even when resting, and suffer from continuous fatigue, chronic coughing, wheezing and frequent respiratory infections. Patients are also at higher risk for lung infection, inflammation and other respiratory conditions, as well as serious other systemic conditions such as diabetes[1] and heart disease.[2]

As there is no cure for emphysema, the goal of current treatment methods such as drug therapy (inhaled steroids, bronchodilators and antibiotics), supplemental oxygen, and pulmonary rehabilitation (breathing exercises) is to relieve symptoms and teach people how to live with the disease. Eventually, the disease will exhaust these treatment methods, leaving the patient with very few options for symptom relief.[3]

About PneumRx Inc.

PneumRx, Inc. is a Mountain View, CA based medical device start-up focused on developing minimally-invasive solutions for unmet medical needs in pulmonary medicine. The flagship product, the RePneu® Lung Volume Reduction Coil, is designed to reduce lung volume and restore elastic recoil to improve lung function, exercise capacity, and quality of life for patients with emphysema. Made from shape-memory Nitinol, the RePneu Coil is designed to compress hyperinflated tissue and tether small airways to prevent airway collapse without blocking airways or inducing fibrosis. The RePneu LVRC is limited to investigational use in the U.S.A. Read more at www.pneumrx.com.

[1] Emma H Baker MD and Derek Bell MD. *Blood glucose: of emerging importance in COPD exacerbations*. Thorax 2009;64:830-832.

[2] Kaiser Permanente Medical Care Program. COPD and Incident Cardiovascular Disease Hospitalizations and Mortality. Chest 2005; 128: 2068-075

[3] Centers for Disease Control and Prevention. Chronic Obstructive Pulmonary Disease Surveillance – United States, 1971-2000. Morbidity and Mortality Weekly Report. August 2, 2002; 51(SS06):1-16.

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