PneumRx, Inc. Receives FDA Approval to Commence Pivotal Clinical Trial of RePneu Lung Volume Reduction Coil System

MOUNTAIN VIEW, Calif./PRNewswire/ -- PneumRx, Inc. (www.pneumrx.com [1]), a medical device company dedicated to bringing innovation and improvements to the treatment of lung disease, today announced that it has received FDA approval to commence a 30-site pivotal clinical trial to support a PMA application for the RePneu LVRC System.
The RePneu LVRC System is a minimally invasive device intended to improve lung function in emphysema patients by bronchoscopically implanting Nitinol coils into the lungs to compress diseased tissue (lung volume reduction), restore elastic recoil, and adjust lung compliance. This treatment offers a minimally invasive alternative to lung volume reduction surgery to a broad range of emphysema patients.

The RePneu LVRC has already undergone extensive clinical studies in Europe, with impressive results in over 250 treatments. The majority of subjects who underwent RePneu LVRC treatment in PneumRx's European clinical trials experienced significant improvement in lung function, exercise capacity and quality of life at both 6 months and one year after treatment, with minimal risk. 74% of all clinical subjects maintained a clinically significant improvement in exercise capacity at 12 months post-treatment and 96% experienced significant improvement in quality of life.

Specifically, RePneu LVRC subjects experienced a mean improvement in Six-Minute Walk Test of 62 meters; a 12% increase in FEV1, a 10% decrease in Residual Volume and a decrease of 12 points in the St. George's Respiratory Questionnaire, at 12 months. The European clinical trial results were used to support PneumRx's CE Mark, and the RePneu LVRC System has been commercially available in Europe since 2010.

The RePneu LVRC has proven effective in patients with both heterogeneous and homogeneous disease, in both the upper and lower lobes, and it works independently of collateral ventilation. The safety profile of the RePneu LVRC System is comparable to that of a simple bronchoscopy procedure, with the majority of adverse results occurring, and resolving, within 30 days of treatment. Patients generally return home from the hospital the day after the treatment.

"We are thrilled to have IDE approval for the RePneu LVRC and are eager to bring this exciting technology to the United States," said Erin McGurk, PneumRx's President and CEO. "It has been so gratifying to see the benefits the RePneu LVRC treatment has brought to emphysema patients in Europe and we are especially pleased to be able to bring these benefits to a greater number of patients suffering from this debilitating disease here in the United States. We plan to treat over 300

subjects in our pivotal trial, and expect to start enrolling clinical subjects in the coming months. We look forward to submitting the pivotal trial results in support of a PMA application to sell the RePneu LVRC System in the United States."

"The entire PneumRx team, in partnership with our accomplished team of Physician Advisors, has worked tirelessly to support the RePneu LVRC IDE application and design an appropriate clinical trial," stated Kara Andersen Reiter, Vice President of Regulatory Affairs at PneumRx. "We are grateful to the FDA team who reviewed our IDE application and worked with us to bring our submission over the finish line."

About PneumRx, Inc.
PneumRx, Inc. is a rapidly growing medical device company focused on the development and commercialization of innovative products to treat emphysema using minimally-invasive techniques. It is a privately held company located in Mountain View, California.

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