



Spiration, Inc. Announces First Patient Enrollment in U.S. Pivotal Trial of Minimally Invasive Treatment for Severe Emphysema

IBV[®] Valve System May Improve Quality of Life for Patients

Living with Debilitating Condition

Redmond, Wash. – Sept. 26, 2007 – Spiration, Inc., a developer of novel medical technology designed to benefit patients with acute and chronic conditions of the lung, today announced that the first patients have been enrolled in the company's IBV Valve Trial in the United States. The purpose of the trial is to generate safety and effectiveness data for submission to the U.S. Food and Drug Administration (FDA) for approval to market the company's IBV Valve System in the United States for the treatment of patients with severe emphysema.

"More than three million Americans are living with emphysema, a condition that is chronic and severely impacts quality of life," said Rick Shea, president and CEO, Spiration[®]. "We are excited about the milestone that the initiation of this pivotal trial represents for Spiration and for patients with severe emphysema, many of whom do not respond well to current medical treatments or are not eligible for major surgery such as lung volume reduction or lung transplantation."

The first patients were enrolled in the pivotal trial by Daniel Nader, DO, FCCP, clinical assistant professor of internal medicine and director of the Oklahoma State University Center for Respiratory Medicine in Tulsa, Oklahoma.

"There are currently few treatment options for people with severe emphysema, who struggle with each breath and therefore cannot do very simple things that most people take for granted, such as simultaneously walking and talking," said Dr. Nader. "Spiration's valve therapy – which is much less invasive than lung surgery – may one day offer a new treatment option to improve quality of life for these patients."

The IBV Valve Trial is a prospective, randomized, blinded clinical trial that will enroll up to 500 patients at up to 40 sites in the United States. The objective of the study is to demonstrate the safety and effectiveness of the IBV Valve treatment. The primary endpoints of the study will be



measured at six months. Patients enrolled in the control arm of the study will be eligible to receive treatment with the IBV Valve System after completion of the six-month study period.

For the treatment of emphysema, the IBV Valve System is designed to redirect airflow from diseased portions of the lung to healthier areas. During the minimally invasive procedure, a catheter is passed through a bronchoscope (a flexible tube passed into the bronchial tubes through the mouth or nose) to deploy the small umbrella-shaped valves into the airways of the upper lobes of the lungs. Although the valves are intended to be permanent, they are designed to be removed via a minimally invasive procedure if necessary.

The IBV Valve Trial design is based on results of a pilot study. “Findings of the pilot study are encouraging, and suggest that the IBV Valve may provide improvements in quality of life for many patients. We hope to confirm these results in the pivotal trial,” said Daniel Sterman, M.D., director of Interventional Pulmonology of the University of Pennsylvania Medical Center in Philadelphia, who presented further results from the pilot study last week at the European Respiratory Society’s Annual Congress in Stockholm, Sweden.

Study investigators are actively recruiting patients for the IBV Valve Trial. The study is open to men and women age 40 to 74 who have been diagnosed with predominantly upper lobe emphysema and shortness of breath with exertion. Eligible patients are able to participate in pulmonary function and standardized exercise tests, have not smoked for four months and are willing to not smoke during the trial. Additional criteria must be met for participation in the study. For more information, including trial site locations, please visit www.emphysematrial.com or call (877) 547-8839.

About Emphysema

Emphysema, a component of Chronic Obstructive Pulmonary Disease (COPD), is a common, debilitating lung disease with no cure in which the tiny air sacs that make up the lungs (alveoli) are enlarged or destroyed. This impairs the exchange of oxygen and carbon dioxide with the blood, reduces the lungs’ ability to exhale air, and is accompanied by coughing and breathing difficulties, initially with exertion and eventually also while at rest. The most common cause of emphysema is an inflammatory reaction to inhaled smoke. Currently available treatments for emphysema are generally palliative and include medications, home oxygen therapy, pulmonary rehabilitation, lung volume reduction surgery and lung transplantation.



About Spiration's IBV Valve System

Spiration's IBV Valve System is a minimally invasive device under investigation in the U.S. for the treatment of severe emphysema. The system has received CE Mark approval for the treatment of diseased and damaged lung in Europe and is an investigational device in Canada.

About Spiration Inc.

Spiration Inc. is committed to improving quality of life for patients with acute and chronic conditions of the lung through the development of novel therapies. Founded in 1999 in Redmond, Wash., the privately held company is backed by prominent investors including Three Arch Partners, New Enterprise Associates, Versant Ventures, New Leaf Ventures, InterWest Partners, Investor Growth Capital, GE Capital, Boston Scientific Corporation and Olympus Medical Systems Corporation. For more information, visit the company's website at www.spiration.com.

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