



**Spiration, Inc. Announces Positive Results from Pilot Study of Treatment for  
Patients with Severe Emphysema at  
European Respiratory Society's Annual Congress**

*Results Provide Insight into IBV® Valve Mechanism of Action;  
Design of European Study Also Presented*

**Redmond, Wash. and Stockholm** – September 19, 2007 – Spiration, Inc., a developer of novel medical technology designed to benefit patients with acute and chronic conditions of the lung, today reported further results of a pilot study of its IBV Valve System for patients with severe emphysema. Data were presented at the European Respiratory Society's Annual Congress in Stockholm by Daniel Sterman, M.D., director of Interventional Pulmonology at the University of Pennsylvania Medical Center in Philadelphia.

“Encouraging results continue to indicate that Spiration’s treatment holds promise for improved quality of life 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,” said Dr. Sterman. “There are currently few treatment options for these patients. I am excited that Spiration’s therapy may offer hope.”

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.

***Retrospective Subset Analysis Provides Insight into Treatment's Mechanism of Action***

In another session during the conference, Steven Springmeyer, M.D., FCCP, vice president and medical director for Spiration, presented a retrospective subset analysis of data from U.S.



patients enrolled the IBV Valve System pilot study that concluded that most responses to bronchial valve treatment for emphysema are due to redirection of inspired airflow.

“This analysis broadens our understanding of this innovative treatment for emphysema, providing insight into the mechanism of action of the IBV Valve System and demonstrating that overall lung volume reduction is not necessary to achieve a clinically meaningful improvement in quality of life,” said Dr. Springmeyer. “Spiration is pleased with these results and with the progress we have made with the IBV Valve System to date. We are looking forward to enrolling the first patients in the U.S. pivotal trial of the IBV Valve in the near future.”

### ***Design of Randomized, Blinded European Study Presented***

Earlier at the conference, on Sunday, September 15, Vincent Ninane, M.D., of the St. Pierre Hospital in Brussels, Belgium presented details about the design of Spiration’s current European clinical study of the IBV Valve System.

“The use of valves to block airflow to areas of severe emphysema has been shown to be safe, with reports of improved quality of life. However, these studies have been case series without blinding,” said Dr. Ninane. “Since health status improvements can be influenced by placebo effects, effectiveness evaluations require a rigorous clinical study design. The European study of Spiration’s therapy is the first and currently the only announced study of a bronchial valve to meet these rigorous requirements.”

The objective of the European clinical study of the IBV Valve System is to augment the clinical data used to obtain the CE Mark with data from a randomized, blinded study. Study endpoints are lung volume changes as measured by CT scan quantification and changes in disease specific health status as measured by the St. George’s Respiratory Questionnaire in patients who have been randomized and are blinded to either treatment or control groups.

The first patients were enrolled in the European study in April 2007. Investigators are actively recruiting patients. 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 study. Additional criteria must be met for participation in the study. For more information, including trial site locations, please visit [www.spiration.com](http://www.spiration.com).

### **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 the 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](http://www.spiration.com).

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