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Spiration Announces Positive Results of European Study Evaluating Safety and Effectiveness of Bronchial Valve Treatment for Severe Emphysema

New Understanding of Mechanisms of Action of Bronchial Valve Treatment

Redmond, Wash. and New Orleans, La. – May 19, 2010 – Spiration, Inc., a developer of novel medical devices designed to benefit patients with severe and chronic conditions of the lung, today shared results from a European study of the company’s bronchial valve treatment for severe emphysema in a number of presentations at the annual American Thoracic Society (ATS) International conference in New Orleans, La.

“The European study of the IBV Valve System contributes to the growing body of positive results for safety and effectiveness of the IBV Valve for the treatment of severe emphysema. Patients in the treatment group met a threshold of change in lung volume and quality of life that was significantly better than the control group. In addition, we were very pleased that no pneumothorax was observed in patients receiving valve treatment,” said Vincent Ninane, M.D., of the St. Pierre Hospital in Brussels, Belgium, one of the presenters at ATS.

Pneumothorax, a condition in which air accumulates in the space that surrounds the lung, can become life-threatening.

“The European study of Spiration’s therapy is the first randomized, blinded, sham-controlled study of a bronchial valve, which is an important milestone for the field,” continued Dr. Ninane.

The randomized European study of the IBV Valve System enrolled 73 patients at seven centers in six countries. After baseline tests, including a quantitative computed tomography (CT) scan, patients were randomized to either the treatment arm, in which patients received valve placement in both upper lobes of the lung, or the control arm, in which patients underwent an observational bronchoscopy but received no bronchial valves. After a three-month evaluation, all patients were informed of whether they had been part of the treatment or control group. Control patients were then eligible for valve treatment.

Endpoints of the European study were lung volume changes as measured by quantitative CT scan and changes in disease-specific health status as measured by the St. George’s



Respiratory Questionnaire (SGRQ). An analysis of the data found that only patients in the treatment group were responders, having both changes in lung volume as measured by quantitative CT scan and a clinically meaningful improvement in quality of life as measured by SGRQ.

Safety outcomes for the European study were positive, with no unanticipated adverse events reported. The most common adverse event was exacerbation of chronic obstructive pulmonary disease (COPD). Overall procedural safety for patients receiving treatment was highly acceptable and compared favorably to the control group.

“As we gather data from studies and from clinical practice with the IBV Valve, we are learning more about potential mechanisms of action of the device,” said Rick Shea, president and CEO of Spiration. “We understand now that there are at least three different mechanisms of action of the bronchial valves, which correspond to various treatment algorithms and patient outcomes.”

A recent publication of the results of the U.S. Pilot Study of the IBV Valve System (“A Multicenter Pilot Study of a Bronchial Valve for the Treatment of Severe Emphysema”, *Respiration*, 2010;79:222–233) outlined three known mechanisms for improvement with bronchial valve treatment: 1.) reducing overall lung volume by blocking all airways in a lung lobe, an approach that can emulate lung volume reduction surgery; 2.) reducing dynamic hyperinflation, a condition that limits exhalation of air before taking another breath; and 3.) redirecting airflow from diseased portions of the lung to healthier areas. These mechanisms of action are not mutually exclusive.

The European study focused on one of three known mechanisms of action using a treatment algorithm in which valves are placed in both upper lobes of the lungs without producing lobar collapse. The goal of treatment is to shift inspired air from the treated to the untreated, healthier lower lobes and consequently improve the patient’s quality of life.

Mark R. Elstad, M.D., chief of medicine at the Salt Lake City VA Medical Center and professor of internal medicine (pulmonary) at the University of Utah, presented a retrospective analysis of data from 359 patients from multiple studies that examined three treatment algorithms and safety results regarding pneumothorax. The results highlight the enhanced safety for the bilateral treatment algorithm utilized in the European study.



About the IBV Valve System

The IBV Valve System is a minimally invasive treatment that has diverse applications in both acute and chronic conditions of the lung. 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 lungs. The valves are designed to be removed via a similar bronchoscopic procedure.

The device has received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy, or lung volume reduction surgery. The effectiveness of this device for this use has not been demonstrated.

The IBV Valve System is currently under investigation in the U.S. as a new treatment option for the many people with severe emphysema who do not respond well to current medical therapies or are not eligible for or elect not to undergo invasive surgery such as lung volume reduction or lung transplantation.

The IBV Valve System is marketed and distributed by Olympus in Europe, where the system has received market clearance through the CE Mark for the treatment of diseased lung in emphysematous patients or damaged lung resulting in air leaks by limiting airflow to selected areas. Olympus also has exclusive development and distribution rights for the IBV Valve System in Japan.

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 (Sprout Group), InterWest Partners, Investor Growth Capital, Saints Capital and Olympus Medical Systems Corp. For more information, visit the company's website at www.spiration.com.

Information about the U.S. pivotal study of Spiration's IBV Valve System may be found at www.emphysematrial.com.

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Cautions: Humanitarian Use Device. Authorized by Federal (or United States) Law for the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy, or lung volume reduction surgery. The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician. IBV Valve is not yet approved for use in emphysema, but is subject to an ongoing clinical investigation in which approval for use in emphysema will be sought.