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CSA Medical Commences Phase B of the RejuvenAir System Safety and Feasibility Study For the Treatment of Chronic Bronchitis Patients

Chronic Bronchitis clinical study milestone achieved on World COPD Day

Lexington, MA – November 16, 2016: CSA Medical, Inc., a company focused on developing spray cryotherapy devices that selectively freeze and ablate unwanted tissue inside the body, today announced the company has begun Phase B of its clinical study to evaluate the safety and feasibility of treating Chronic Bronchitis patients with the RejuvenAir® System.

November 16 is World COPD Day. Started in 2002, World COPD Day was designed to raise awareness of COPD, and promote early diagnosis of the disease. Chronic bronchitis is a subset of COPD, and currently has limited treatment options.

Three of the patients that were previously treated in phase A of this first feasibility study have undergone their second treatment, marking the start of Phase B of the study. Dr. Dirk-Jan Slebos, M.D., PhD in the Department of Pulmonary Diseases at University Medical Center Groningen, The Netherlands performed these treatments.

All patients enrolled in Phase A of the study, which consisted of treating the right lower lobe and right main stem of the right lung, will be scheduled for their second treatment, which will treat the left lower lobe and left main stem of the left lung. A third treatment will follow 30-45 days later, which will treat the upper lobes of both lungs and trachea, completing the therapy.

"The initiation of Phase B of this study is a major step forward as these patients will now be treated with the full therapy. We will continue to monitor improvements in the patients SGRQ scores to assess the potential for a positive impact to the lives of chronic bronchitis patients." said Ellen Sheets, MD, CEO CSA Medical.

The RejuvenAir® System is designed to spray liquid nitrogen at -196°C in a circumferential pattern within the airway. It is anticipated that the rapid freezing of the epithelial layer of the airway walls will destroy the mucus-producing goblet cells while preserving the extracellular matrix, thereby enabling the regrowth of healthy cells.

The Safety and Feasibility Study of RejuvenAir for Treating Chronic Bronchitis Patients (NCT02483637) is a prospective, open label, single arm, two phase study with sequential accrual of patients with known chronic bronchitis. Phase A enrolled 11 patients and treated a single lobe to assess safety, feasibility and histologic/immunologic response. Phase B of the study began after review and approval of the Phase A data by the Data Safety Monitoring Board. In Phase B of the

study, Phase A patients will have their remaining lobes treated. In Phase B, up to 24 additional patients will be enrolled. Once all patients have received complete treatment of both lungs they will be periodically followed for safety and physiologic response of their underlying chronic bronchitis to this novel treatment.

About Chronic Bronchitis

Chronic Bronchitis is the largest disease subset of Chronic Obstructive Pulmonary Disease (COPD). Bronchitis is inflammation of the bronchial airways. A chronic bronchitis diagnosis is defined by cough with productive sputum of three months duration for two consecutive years. In addition to a chronic inflammation, cough and increased production of mucus, chronic bronchitis may or may not present with obstruction/partially blocked airways due to swelling and excess mucus in the bronchi, or shortness of breath (dyspnea).

In the United States, there are an estimated 12.7 – 14.7 million people with COPD¹, and in 2011 approximately 10 million people sought medical attention for chronic bronchitis, a subset of COPD.² Approximately 700,000 people are hospitalized for symptoms/exacerbations of chronic bronchitis every year³.

In Europe, there are approximately 23 million people with COPD⁴. There are approximately 1.5 million hospitalizations per year for COPD⁵.

About CSA Medical

CSA Medical, Inc. develops and manufactures a proprietary interventional spray cryotherapy technology platform utilizing unique properties of liquid nitrogen spray delivered by a software driven device with specialty catheters that enable delivery of spray cryogen inside the body to flash freeze and destroy unwanted tissue allowing for a rejuvenative pattern of healing.

The RejuvenAir System is currently under clinical investigation and is not commercially available.

To learn more about our technology, please visit www.csamedical.com.

RejuvenAir is a registered trademark of CSA Medical, Inc.

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¹ American Lung Association, Trends in COPD: Morbidity and Mortality.
<http://www.lung.org/finding-cures/our-research/trend-reports/copd-trend-report.pdf>

² ibid

³ CDC/NCHS National Hospital Discharge Survey, 2010.

⁴ Health at a Glance: Europe (2012 and 2014 reports) http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2012_9789264183896-en

⁵ erswhitebook.org