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CSA Medical Announces the First Chronic Bronchitis Patient Treatments in the RejuvenAir® System Safety and Feasibility Study

Patient treatments occurred at two sites for the initiation of the clinical study.

Lexington, MA – April 12, 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 initiated treatments in a clinical study to evaluate the safety and feasibility of treating Chronic Bronchitis patients with the RejuvenAir® System.

The first treatment was successfully performed at the University Medical Center Groningen in Groningen, The Netherlands on March 22. Dirk-Jan Slebos, M.D., PhD in the Department of Pulmonary Diseases at University Medical Center Groningen performed the first treatment.

"This first ever treatment using the RejuvenAir® System functioned as anticipated with smooth delivery of the liquid nitrogen Metered Cryospray™ allowing us to safely complete the anticipated treatments in the right lower lobe. The team looks forward to continued enrollment for this initial safety and feasibility trial for our highly symptomatic chronic bronchitis patients," said Dr. Slebos.

The second treatment was successfully performed in London, England on March 23. The research team led by Dr Pallav Shah MD, MBBS, FRCP, Consultant Physician at Royal Brompton Hospital and Chelsea and Westminster Hospital, treated the first UK patient with revolutionary new cryospray system for patients with chronic cough and sputum production.

"The RejuvenAir System cryospray treatment is an exciting new therapy for the challenging symptoms in patients with Chronic Bronchitis where currently the only option is to reduce the thickness of the mucus with medication," said Dr. Shah.

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 will enroll up to 12 patients and will treat a single lobe to assess safety, feasibility and histologic/immunologic response. After review and approval of the Phase A data by the Data Safety Monitoring Board, Phase B of the study will begin. 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 COPD[1], 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 year[3].

In Europe, there are approximately 23 million people with COPD[4]. There are approximately 1.5 million hospitalizations per year for COPD[5].

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.

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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