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FOR IMMEDIATE RELEASE

RejuvenAir® Metered Cryospray™ Shows Promise as Treatment for COPD Patients with Chronic Bronchitis

- RejuvenAir® Feasibility Study Results Demonstrate Strong Safety Profile and Clinically Meaningful Improvement on Quality of Life measures at 6-month follow-up in Chronic Bronchitis Patients.

- RejuvenAir® Clinical Development Program to Proceed to Pivotal Study in 2019

Boston, MA – September 18, 2018 - CSA Medical Inc. presented positive results of its feasibility study of the RejuvenAir® Metered Cryospray™ system at the 2018 European Respiratory Society (ERS) Congress in Paris.

In an analysis of 30 patients at 6-month follow up, treatment with RejuvenAir® resulted in clinically meaningful improvement in Quality of Life, as measured by Saint George's Respiratory Questionnaire (SGRQ) and COPD Assessment Test (CAT). The procedure demonstrated a strong safety profile and was well tolerated.

Dirk-Jan Slebos, M.D., PhD of the Department of Pulmonary Diseases, at the University Medical Center Groningen, The Netherlands reported that "The RejuvenAir therapy appears to have a beneficial response with a decrease in cough and mucus production even in our patients who had optimized medical management. The overall improvement in breathing resulted in increased physical activity supporting the potential for RejuvenAir to measurably improve quality of life in chronic bronchitis patients."

"RejuvenAir Metered Cryospray can be safely delivered in patients with COPD and demonstrates clinical meaningful improvements in quality of life and symptom scores (SGRQ and CAT) out to 6 months and is a promising new therapy for the millions of people who suffer from chronic bronchitis," further notes Professor Pallav Shah, M.D., FRCP from the Royal Brompton, London.

Results

As reported at ERS, RejuvenAir® therapy demonstrated strong safety and tolerability profile during the study with minimal procedure related adverse events and serious adverse events. Importantly, there were no pneumothorax or pneumomediastinum events. Patients were able to be discharged from outpatient bronchoscopy suite on day of treatment.

On SGRQ, patients treated with RejuvenAir® improved by an average of 10.9 points ($p<0.02$) at 6-month follow-up. According to peer-reviewed literature, an improvement of 4 points on SGRQ is considered to be clinically meaningful. On CAT, patients treated with RejuvenAir® improved by an average of 3.4 points ($p<0.02$) at 6-month follow-up. According to peer-reviewed literature, an

improvement of 2 points on CAT is considered to be clinically meaningful.

"We are encouraged by these positive safety and feasibility results and we're moving forward with plans to initiate a worldwide pivotal study of RejuvenAir in chronic bronchitis in 2019", said Wendelin Maners, CSA Medical's Chief Commercial Officer, who further stated, "We look forward to advancing this novel therapy toward commercialization to provide relief to the millions of patients suffering from COPD with chronic bronchitis."

Safety and Feasibility Study of RejuvenAir®

The *Safety and Feasibility Study of RejuvenAir for Treating Chronic Bronchitis Patients* (NCT02483637) is a prospective, open label, single arm study of COPD patients with known chronic bronchitis is being conducted at three sites in The Netherlands, United Kingdom, and Canada. The study strongly supports the feasibility of using Liquid Nitrogen Metered Cryospray™ (MCS) throughout the central airways to ablate inflamed bronchial epithelium allowing non-inflamed tissue to regenerate after treatment. Phase A of the study enrolled 11 patients and treated a single lobe to assess safety, feasibility and histologic/immunologic response. In Phase B of the study, Phase A patients had their remaining lobes treated and 24 additional patients were enrolled and treated. All patients have received complete treatment of both lungs and they are being periodically followed for safety and physiologic response of their underlying chronic bronchitis to this novel treatment. Primary endpoints include, 1) adverse and serious adverse events and ability to complete all three treatments, and 2) mean change from baseline total SGRQ score. Secondary endpoints include CAT, 6-minute walk test, spirometry testing, and other objective pulmonary function tests and patient reported outcome instruments. Exacerbation rate was measured as an exploratory endpoint.

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, and in 2011 approximately 10 million people sought medical attention for chronic bronchitis, a subset of COPD. Approximately 700,000 people are hospitalized for symptoms/exacerbations of chronic bronchitis every year. In Europe, there are approximately 23 million people with COPD. There are approximately 1.5 million hospitalizations per year for COPD.

About RejuvenAir®

The RejuvenAir® Metered Cryospray™ 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 RejuvenAir® System is currently under clinical investigation and is not commercially available.

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. CSA technology Liquid Nitrogen (LN2) spray that has a boiling point of -196^{o}C to ablate unwanted benign and malignant tissue. 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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