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CSA MEDICAL
Freeze disease®

CSA Medical Inc.
91 Hartwell Avenue
Lexington, MA 02421

781.538.4720 tel
781.538.4730 fax

CSA Medical, Inc. Announces European Approval for its RejuvenAir® System for COPD Patients with Chronic Bronchitis

- Approval based on study showing both safety and clinically meaningful improvement in patient quality of life -

Boston, MA – December 2, 2019: CSA Medical, Inc., today announced that it has received CE Mark approval for its' RejuvenAir® System for the treatment of Chronic Obstructive Pulmonary Disease (COPD) with Chronic Bronchitis (CB). The RejuvenAir System is a revolutionary cryosurgical device which applies Metered Cryospray ("MCS") of liquid nitrogen at -196◦C to targeted areas within the lungs through a minimally invasive bronchoscopic procedure. The extreme cold flash freezes damaged surface area lung cells which induces a rejuvenative healing process.

COPD with CB is a long-term, progressive lung disease that, over time, makes it hard to breathe. CB is characterized by a productive cough due to the overproduction of mucus and damaged cilia. According to the American Lung Association, CB affects more than 11 million Americans and is the third leading cause of disease-related deaths.

"While pharmaceutical options can decrease cough and mucus production, the RejuvenAir System offers the only treatment able to address the underlying cause of CB – while simultaneously treating the debilitating symptoms," says Heather Nigro, SVP of Regulatory, Quality and Clinical Affairs at CSA Medical. She continued, "This patient population now has an option that can dramatically improve their quality of life - that's exciting!"

The approval in the EU of this first-of-a-kind technology was supported by a prospective, multi-center, open-label, safety and efficacy study. The 35 patient study led to a significant improvement in patient-reported health-related quality of life, at least up to 12 months. Treatment with the RejuvenAir System was well tolerated and did not result in any significant or unexpected safety events.

"RejuvenAir Metered Cryospray can be safely delivered in patients with COPD and demonstrates clinical meaningful improvements in quality of life and patient-reported outcome scores out to 12 months," said Professor Pallav Shah, M.D., F.R.C.P. from the Royal Brompton, London. "This is a promising new therapy for the millions of people who suffer from chronic bronchitis."

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 now approved in the EU and under clinical investigation in the United States.

About COPD with 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 11 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 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 now approved in the EU and under clinical investigation in the United States. To learn more about our technology, please visit www.csamedical.com

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For further information contact:
Wendelin Maners, CSA Medical
+1-781-538-4748
wmaners@csamedical.com