CSA MEDICAL
Spray Cryotherapy®

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FOR IMMEDIATE RELEASE

CSA Medical, Inc. Receives FDA Breakthrough Device Designation and IDE Approval for its RejuvenAir® System for COPD Patients with Chronic Bronchitis

Boston, MA - April 3, 2019 – CSA Medical today announced that its RejuvenAir® System has been designated as a Breakthrough Device by the U.S. Food and Drug Administration (FDA) and received unconditional IDE (Investigational Device Exemption) approval to initiate a pivotal clinical study to treat patients with moderate to severe chronic obstructive pulmonary disease (COPD) with chronic bronchitis (CB). The RejuvenAir® System utilizes a Metered Cryospray of liquid nitrogen at -196◦C to targeted areas within the lungs.

CSA Medical plans to initiate the pivotal study designed as a prospective, multi-center, blinded randomized (2:1) sham controlled trial using the RejuvenAir® System across 30 sites in the U.S., Europe and Canada with up to 330 subjects. The study's Lead Principal Investigator will be Gerard J. Criner, MD, FACP, FACCP, Chair and Professor, Thoracic Medicine and Surgery, Lewis Katz School of Medicine at Temple University, and Director, Temple Lung Center.

COPD, which includes CB, is a long-term, progressive lung disease that over time makes it hard to breathe. According to the American Lung Association, the disease affects more than 11 million Americans and is the third leading cause of disease-related deaths.

"We are eager to begin this pivotal trial and build on the successful data that was generated from the feasibility study of RejuvenAir®," stated Heather Nigro, Senior Vice President of Regulatory, Quality and Clinical Affairs at CSA Medical, who continued, "Receiving the Breakthrough Device designation from the FDA further highlights the unmet clinical need for this patient population and we are excited to drive the solution for moderate to severe COPD patients with chronic bronchitis."

The Breakthrough Devices Program is designed to facilitate the development and expedite the review of medical devices that provide for a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Benefits from this designation include early and more frequent contact with the FDA in an effort to collaborate and streamline development and regulatory approval.

Wendelin Maners, CSA Medical's President stated, "We are especially encouraged that the FDA approved the IDE unconditionally. The study approval and device designation will allow us to greatly impact the lives of Chronic Bronchitis patients worldwide and collect significant clinical data surrounding our novel system."

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 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 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 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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