1st patient treated in Rejuvenair trial for COPD with chronic bronchitis

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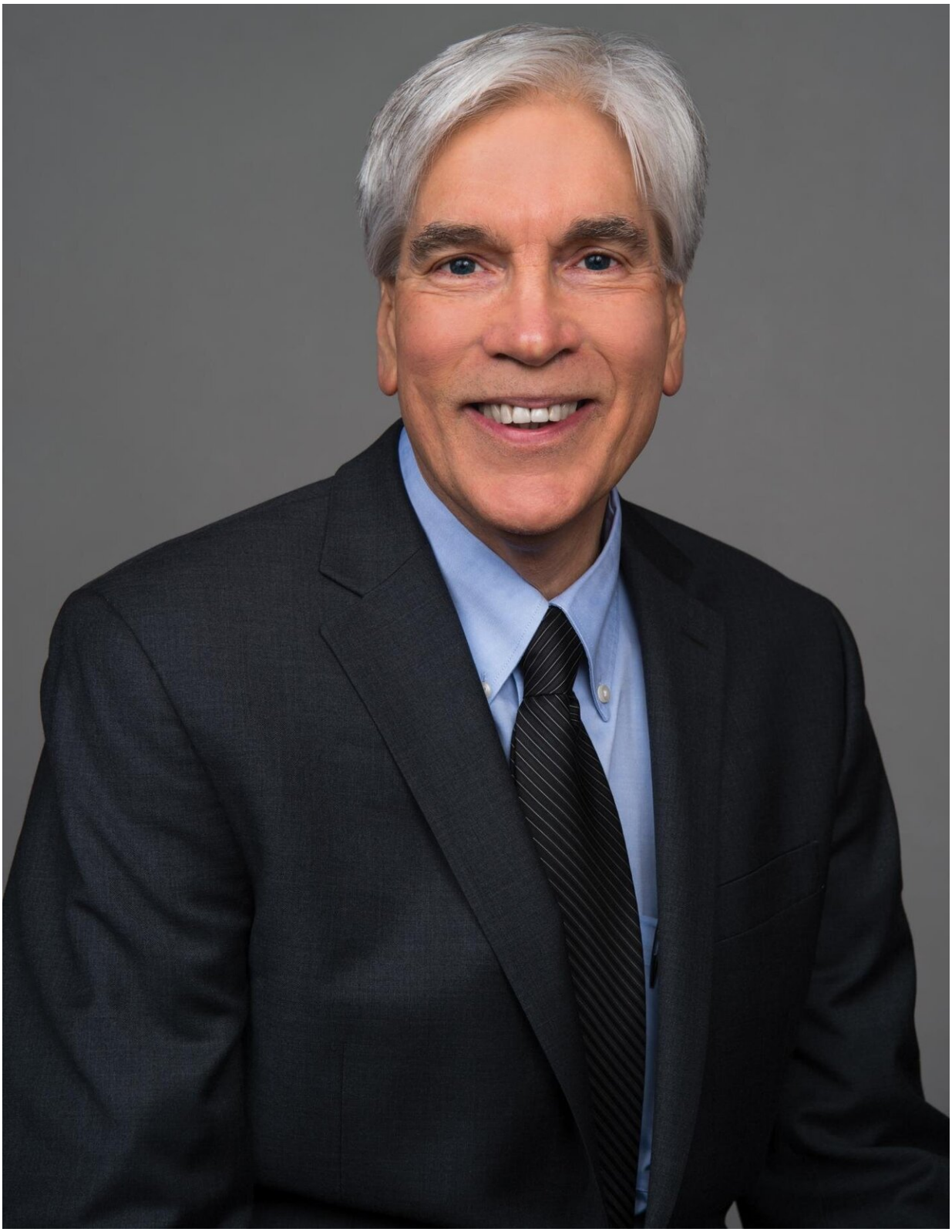

Gerard J. Criner, MD, FACP, FACCP, Chair and Professor of Thoracic

Medicine and Surgery at the Lewis Katz School of Medicine at Temple University and Director of the Temple Lung Center. Credit: Temple University Health System

Temple University Hospital has treated the first patient in a multicenter international clinical trial utilizing the RejuvenAir System for the treatment of patients suffering from moderate to severe chronic obstructive pulmonary disease (COPD) with chronic bronchitis. Chronic bronchitis, a subset of COPD, is characterized by a productive cough that persists for months or years. Chronic bronchitis is especially problematic for patients with COPD because it is associated with a significant daily symptom burden and increases the risk for hospitalization and death.

Chronic bronchitis represents a significant unmet clinical need for patients with COPD; currently there are no approved therapies to effectively treat this condition. As such, the RejuvenAir System was designated as a Breakthrough Medical Device by the Food and Drug Administration in March 2019 and simultaneously received approval under its Investigational Device Exemption (IDE) to begin this double-blind, sham-controlled, prospective, multicenter, randomized clinical trial.

Gerard J. Criner, MD, FACP, FACCP, Chair and Professor of Thoracic Medicine and Surgery at the Lewis Katz School of Medicine at Temple University and Director of the Temple Lung Center, is the overall principal investigator of this multicenter international study.

"This clinical trial offers patients who suffer from COPD with chronic bronchitis a procedural option that has the potential to address more than just symptoms," Dr. Criner said. "We are pleased here at the Temple

Lung Center to be able to expand the treatment and clinical trial options for our patients with this long-term, progressive disease."

The RejuvenAir Metered Cryospray ("MCS") procedure delivers metered doses of liquid nitrogen spray at a temperature of -196 degrees Celsius to targeted areas of the diseased airways. The RejuvenAir System is designed to ablate and instantaneously freeze damaged cilia and mucus-producing cells, thus allowing new, healthy cells to regrow in their place.

COPD affects approximately 16 million Americans, according to the Centers for Disease Control and Prevention (CDC). An estimated 9 million of those individuals have also been diagnosed with chronic bronchitis, a disease subset of COPD. The American Lung Association defines chronic bronchitis as a productive cough (one that produces mucus) lasting for at least three months and occurring multiple times over at least two years. There is no cure for chronic bronchitis or COPD, which is the third-leading cause of death in the United States.

The clinical trial will examine the effectiveness of the RejuvenAir System via two primary outcome measures, exacerbations and quality of life. Acute Exacerbation Rate is calculated from baseline to 12 months post treatment, and the St. George's Respiratory Questionnaire is a patient-reported outcome scale that measures quality of life.

"COPD exacerbations and symptoms greatly impact patients' quality of life," Dr. Criner added. "At the Temple Lung Center, we are committed to research that addresses this, as quality of life is one of our patients' chief concerns."

Provided by Temple University