Aria CV Receives FDA Breakthrough Designation for Its Medical Device for Treating Pulmonary Arterial Hypertension

February 06, 2020 07:00 AM Eastern Standard Time

SAINT PAUL, Minn.--(BUSINESS WIRE)--Aria CV, Inc., a developer of medical devices treating Pulmonary Arterial Hypertension (PAH), today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the Aria CV Pulmonary Hypertension System (Aria CV PH System).

The Breakthrough Devices Program (BDP) is intended to expedite the FDA review and approval of designated devices that may provide more effective treatment of life-threatening or irreversibly debilitating diseases. BDP is intended to help patients gain faster access by expediting designated device development, assessment, and review, while preserving the statutory standards for premarket approval, consistent with the FDA's mission to protect and promote public health.

"Despite the availability of multiple drug therapies, pulmonary hypertension remains a disease with large, unmet needs. Aria's device-based solution has the potential to treat this disease more effectively and with fewer side effects, and the Breakthrough designation provides the opportunity for earlier access to patients," said Gregg W. Stone MD, Director of Academic Affairs for Mount Sinai Heart Health System and a member of Aria's Scientific Advisory Board.

PAH is a progressive, highly debilitating disease that may lead to heart failure. The implanted Aria CV PH System is designed to restore the benefits of a healthy, elastic pulmonary artery, which in turn reduces cardiac workload and enhances blood flow. These benefits have the potential to improve both duration and quality of life.

"The FDA's designation of the Aria CV PH System as a Breakthrough Device affords multiple potential benefits to the company including flexible clinical trial design and facilitated patient access through CMS's revised reimbursement pathway. Our mission is to address the unmet clinical need for this life-threatening disease with an effective treatment option and this designation brings us one step closer to delivering on this mission," said Dan Gladney, CEO and President of Aria CV.

About Pulmonary Hypertension

Pulmonary hypertension is characterized by high blood pressure in the arteries of the lungs, a condition which causes increased workload on the heart, leading to right heart failure. In a common form of the disease, pulmonary arterial hypertension affects mostly women often in the prime of life. Even with currently approved therapy, it is considered a deadly progressive disease.

About Aria CV, Inc.

Based in St. Paul, Minnesota, Aria CV was founded in 2010 by Drs. John Scandurra and Karl Vollmers, following development work the two had done at the University of Minnesota's Earl E. Bakken Medical Devices Center. Aria has performed a successful acute first in human clinical study in Vienna, Austria and is now preparing for a U.S. clinical trial under FDA's Early Feasibility Study Program to evaluate long term implants in PAH patients. Aria CV's major shareholders include Catalyst Health Ventures, Broadview Ventures, Biostar Ventures and a strategic investor.

Contacts

AP Communications
Amy Phillips
amyphillipspr@gmail.com
412.327.9499