Phoenix Cardiac Presents Pivotal Data on its Novel BACE Device at AATS Annual Meeting

Late-breaking oral presentation highlights significant reduction in Functional Mitral Regurgitation (FMR) and left ventricular stabilization

Data presented support recently granted CE Mark for treatment of FMR in EU

Study lays groundwork for second clinical trial and potential U.S. indication for heart failure

Cary, N.C., April 30, 2021 – Phoenix Cardiac Devices, Inc., an innovator in cardiovascular medical device research and development, today will present pivotal data for its BACE™ (Basal Annuloplasty of the Cardia Externally) device, a novel modality for the treatment of Functional Mitral Regurgitation (FMR), at the virtual American Association for Thoracic Surgery (AATS) 101st annual meeting. In a late-breaking presentation, researchers will report positive outcomes including a reduction in the degree of FMR and stabilization of left ventricular function in patients undergoing external cardiac support with the BACE device.[1] The data are the basis of a CE Mark that Phoenix Cardiac recently received for the BACE device, allowing it to be sold on the European market.

A potential alternative to heart valve repair and replacement, BACE is the only surgical device in development with long-term clinical data demonstrating effectiveness in addressing the root cause of FMR by improving coaptation (joining or fitting together of two surfaces) of the mitral valve leaflets while simultaneously providing ventricular support. Phoenix Cardiac is currently seeking a partner to conduct a second clinical trial of the BACE device, and is pursuing a potential U.S. indication for the treatment of heart failure.

"The FMR data presented in the AATS late-breaker session further validate the rationale for external cardiac support with BACE, the only investigational surgical device with implant experience in over 60 patients," said Jai Raman, MBBS, MMed, FRACS, PhD, co-founder and Chief Scientific Officer of Phoenix Cardiac Devices, Inc. and inventor of the BACE device. "BACE addresses dilatation of the left ventricle at the base of the heart, which marks the beginning of the vicious cycle by which FMR progresses to heart failure. BACE is designed to arrest that cycle and stop progression. We demonstrated the proof of concept over 15 years ago, and we continue to accumulate experience with the BACE device. We are confident in its paradigm-shifting potential for the treatment of FMR and heart failure."

In the pivotal study, 44 patients with FMR were implanted with the BACE device at 10 multi-national centers between December 2014 and June 2019, as part of the CE Mark study. Thirty-seven patients underwent concomitant coronary artery bypass grafting (CABG); the mean number of grafts was 2.5. At six months post-operatively, the BACE device met the study's primary endpoint by reducing the degree of FMR to mild or better in 81% of patients ($p<0.0001$), and by achieving stability in FMR. Use of BACE was associated with significant

reductions in markers of FMR severity including mitral annulus diameter (3.35±0.48 to 2.99±0.47 cm) and mitral tenting area (2.5±0.7 to 2.0±1.1 cm^2) from baseline to six months (both p≤0.003). Left ventricular end-diastolic volume decreased from 174.2±41.1 to 138.6±43.2 ml (p<0.001) and remained stable during follow-up (one year: 1.43±45.7 ml; two years: 144±47.2 ml). Patients experienced significant improvement in New York Heart Association (NYHA) functional class heart failure (36% to 12% in Class III-IV) and assessment of heart failure symptoms by the Minnesota Living with Heart Failure Questionnaire (27±18 to 17±17, p<0.001). There were no deaths in the study related to the BACE device.[1]

"The BACE device is novel technology that addresses the root cause of functional mitral valve insufficiency by reducing both annular and sub-annular dilation of the ventricle," commented Thomas M. Beaver, MD, MPH, professor and chief of the Division of Cardiovascular Surgery at the University of Florida College of Medicine, and a member of the Phoenix Cardiac Scientific Advisory Board. "This unique device has shown it reduces MR, keep patients stable and fills a global need for this type of therapy. The BACE device has potential to help the growing number of patients with heart failure, and we look forward to the proposed clinical trial in this setting."

About Functional Mitral Regurgitation (FMR)

FMR (functional mitral valve regurgitation) occurs when blood leaks backward through the mitral valve into the left atrium each time the ventricle contracts, due to abnormal function of the heart muscle. This leads to increased blood volume and pressure in the left atrium. The result is a damming of blood in the lungs, causing shortness of breath and other debilitating symptoms. To maintain forward blood flow, the ventricle must pump harder, leading to enlargement of the left atrium and eventually the left ventricle, setting in motion the progressive downward spiral toward serious and potentially life-threatening complications such as congestive heart failure. FMR is different from leaking of the mitral valve when the valve is structurally abnormal. All current treatment modalities for mitral regurgitation address abnormalities of the valve. There are no specific devices to address Functional Mitral Regurgitation. FMR affects more than 2% of the global population[2], including approximately five in 10,000 individuals in the United States[3], and has a prevalence that increases with age.[2]

About the BACE™ device

BACE is designed to be far less invasive than heart valve repair or replacement because the device sits outside the heart, eliminating the need for open-heart surgery. The device serves as a broad tension band of silicone that encircles and supports the exterior of the heart, allowing the leaflets of the mitral valve to close properly, thereby preventing blood from leaking backward when the heart pumps. BACE can be placed around the heart while it is beating to avoid the use of a heart-lung bypass machine. The device is placed outside the heart, and has no direct contact with blood flow, thus limiting the risk of thrombosis, stroke, and infection. These are complications that commonly occur with devices implanted within the heart. Additionally, the device's placement on a beating heart allows its efficacy and impact to be immediately assessed in real time with an echocardiogram. The device can be tightened remotely and this allows selective application of pressure to support the muscle around the mitral valve. This adjustment is easily performed by adding or removing saline from four inflatable chambers built into the tension band.

About Phoenix Cardiac Devices, Inc.

The mission of Phoenix Cardiac Devices, Inc. is to design, develop, and market new and innovative patented technologies in the cardiac medical device field. Each technology will fulfill a currently unmet need in cardiovascular medical procedures by improving upon existing technology, or be designing a device to serve a need that is clearly defined and acknowledged by medical professionals. Phoenix Cardiac Devices, Inc. was founded in 2012 by President and Chief Executive Officer Gopal Muppirala and Chief Scientific Officer Jai Raman, MBBS, MMed, FRACS, PhD, an academic cardiothoracic surgeon and inventor of the BACE™ (Basal Annuloplasty of the Cardia Externally) device, a novel modality for the treatment of functional mitral regurgitation (FMR). The company has offices in Cary, N.C. and Hyderabad, India. For more information, visit phoenixcardiac.com.

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