



CHICAGO, Jan. 14, 2013 /PRNewswire/ -- Phoenix Cardiac Devices, Inc., a medical device company with a novel method of repairing leaky heart valves without open-heart surgery, has enrolled its first patient in a clinical trial aimed at achieving CE Mark approval in Europe.

The trial will assess the safety and efficacy of the BACE™ device, an adjustable tension band that encircles the heart and supports the mitral valve leaflets so they close properly to prevent the back flow of blood into the heart. Known as mitral regurgitation, the leakage of blood backward into the left atrium contributes to the development of congestive heart failure.

Previous studies of BACE, including a proof of concept study in 12 patients and a feasibility study in 14 patients, demonstrated a significant reduction in mitral regurgitation and no device-related serious adverse events following implantation. Results of the proof of concept study were published in the Australian journal, *Heart, Lung and Circulation* in December, 2009.

The current study will enroll 60 patients in India and Europe who have moderate to severe functional mitral regurgitation. Patients will undergo implantation of BACE, a device designed by a cardiothoracic surgeon to prevent many of the complications that occur with traditional surgical repair of mitral valves. Such complications are due, in part, to open-heart surgery, which requires temporarily stopping the heart and pumping blood through a heart lung by-pass machine during the procedure.

"Our device sits outside the heart, so there is no need to open the heart and no contact with blood flow, both of which are associated with an increased risk of thrombosis, stroke and infections," said Jai Raman , MD, PhD, inventor of BACE.

"Moreover, BACE alleviates the root cause of functional mitral regurgitation – dilated and weakened heart muscle – whereas current surgical treatments focus on replacing or repairing valves that are structurally normal," said Raman, professor of surgery, director of adult cardiac surgery, and surgical director of transplantation at Rush University Medical Center in Chicago.

Among its unique features, BACE can be remotely adjusted from an external port, and its efficacy can be assessed through real-time echocardiography, allowing for immediate adjustments in tension and pressure.

The goal of BACE is to provide a more effective and less invasive method of treating mitral regurgitation that reduces complications and thus lowers the risk of mortality, according to Gopal Muppирala , CEO and co-founder of Phoenix Cardiac Devices. As a closed heart procedure, implantation of BACE may also reduce operating times and hospital stays, resulting in significantly lower costs than with open-heart procedures.

"The current standard of care was developed nearly 40 years ago and, with the advances in technology, there is both an opportunity and a critical need for less invasive and more effective

treatments," Muppirala said.

About Phoenix Cardiac Devices

The mission of Phoenix Cardiac Devices, Inc. is to design, develop, and market innovative, patented technologies in the cardiac medical device field. The company's first product, currently in human trials, is a device that treats functional mitral regurgitation.

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