

Mardil Inc. Advances Its Novel Cardiac Device to First-In-Human Trials for Mitral Valve Regurgitation

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RESEARCH TRIANGLE PARK, N.C., Jan. 26 /PRNewswire/ -- Mardil Inc., a cardiac device company with novel technology for treating mitral valve regurgitation, has successfully advanced its device to first-in-human testing, a milestone achievement for the 2-year-old company.

The first patient was successfully implanted with the Mardil device last month in India. The patient had a significant improvement in heart function after the procedure, according to preliminary data from a 20-patient pilot study. Pending U.S. Food and Drug Administration approval of the clinical protocol, Mardil will launch a multinational clinical trial in the U.S., Canada, Israel, Australia and Europe in the fall of 2009.

"Mardil's concept is truly revolutionary in its approach in that the device simultaneously treats valvular dysfunction while supporting the weakened ventricular muscle, the latter of which is not being adequately addressed by the current therapies on the market," said Dr. Lishan Aklog, chief of cardiovascular surgery at St. Joseph's Hospital in Phoenix, Ariz. Mitral regurgitation occurs when the mitral valve leaks blood backward into the heart, a condition that often leads to congestive heart failure and severe, debilitating symptoms. Current treatments for the condition, however, carry a range of serious complications and risks.

The average mortality rate for patients undergoing mitral valve repair and coronary artery bypass surgery together has risen to 10 percent, a statistic that Mardil founders hope to reduce with their device.

The Mardil device, called BACE(TM) (Basal Annuloplasty of the Cardia Externally), was pioneered by cardiothoracic surgeon Dr. Jai Raman in his efforts to develop a minimally invasive approach to treating mitral regurgitation.

"We designed BACE to reduce the significant costs, side effects and mortality rates associated with current mitral valve repair and replacement techniques," said Gopal Muppurala, chief executive officer and co-founder of Mardil. "Our device is minimally invasive in that it sits outside the heart and does not require open heart surgery or stopping the heart to implant the device."

BACE represents a departure from current devices because it addresses the root cause of the condition: a heart muscle that is weakened, stretched and enlarged, according to Raman, professor of surgery and director of adult cardiac surgery and cardiothoracic surgical research at the University of Chicago.

"The Mardil device is the next-generation treatment for mitral valve regurgitation," said Raman. "BACE corrects the functional abnormality that leads to mitral regurgitation, whereas current devices on the market focus on replacing or repairing valves that are structurally normal."

In addition, the novel feature of BACE is that it can be remotely adjusted through ports under the skin that funnel saline to and from four inflatable chambers built into the tension band. The efficacy of BACE can be assessed at the time of implantation through a real-time echocardiogram, allowing for immediate adjustments in pressure.

The company is now finalizing its multinational clinical trial protocol for submission to the FDA this summer.

ABOUT MARDIL INC.

Mardil Inc. is a medical device company with a mission to design, develop and market innovative, patented cardiac technologies. Each technology will fulfill a current unmet need in cardiovascular medical procedures by improving upon an existing technology or by designing new technology that more effectively treats cardiovascular conditions. The company's first product is a minimally invasive device that treats functional mitral valve regurgitation. The device is currently in human trials.

SOURCE Mardil Inc.