

CardiAQ Valve Technologies

Transcatheter Mitral Valve Implantation

NEWS RELEASE

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CardiAQ™ Valve Technologies reports cardiovascular medicine milestone: first-in-human nonsurgical percutaneous implantation of a bioprosthetic mitral heart valve

Nearly 50% of patients suffering from a diseased mitral heart valve with severe, symptomatic regurgitation are denied open-heart surgery because it is considered too risky; in the future, Transcatheter Mitral Valve Implantation (TMVI) may offer new hope for these patients.

IRVINE, Calif., June 14, 2012—CardiAQ Valve Technologies (CardiAQ), which has developed the world's first self-conforming and self-anchoring technology for nonsurgical Transcatheter Mitral Valve Implantation (TMVI), today announced that the Company has achieved a cardiovascular medicine milestone: a bioprosthetic mitral heart valve was successfully implanted as a compassionate treatment into an 86-year-old male suffering from severe mitral regurgitation (MR 4+). The breakthrough TMVI procedure was performed on June 12, 2012, at The Heart Centre, Rigshospitalet University Hospital, Copenhagen, Denmark, by interventional cardiologists Lars Søndergaard, M.D., and Olaf Franzen, M.D., cardiovascular surgeon Susanne Holme, M.D., anesthesiologist Peter Bo Hansen, M.D., and echocardiographer Nikolaj Ihlemann, M.D.

“Our TMVI system is designed to make nonsurgical mitral heart valve replacement a future alternative to open-heart surgical replacement and repair,” said Rob Michiels, CEO of CardiAQ Valve Technologies. “CardiAQ is currently the only transcatheter-transvessel implantation approach to treating MR. While several companies have been trying to perfect a percutaneous approach to repair the mitral valve, we believe that such technologies will have a very difficult time demonstrating sufficient efficacy in treating such a heterogeneous disease,” added Michiels. “CardiAQ’s nonsurgical valve implantation approach is designed to become a disruptive technology with a much broader application.”

“CardiAQ has focused on replacement or implantation—not repair—for three reasons: Replacement of the diseased mitral valve offers (1) the best chance of eliminating regurgitation, (2) the widest applicability across patient and disease variations, and (3) can be made into a simple, fast, straightforward interventional—i.e., nonsurgical—procedure,” said Brent Ratz, co-founder and COO.

“As cardiac surgeons, we are taught that residual mitral regurgitation will only lead to more mitral regurgitation and progressive symptoms. That is why we have focused our efforts on developing a replacement technology with the potential to eliminate clinically significant MR, not just reduce it,” said Arshad Quadri, M.D., chairman, founder/inventor and CMO of CardiAQ. “Moreover, many of these inoperable patients suffer from functional MR, which is actually a result of ventricular dilatation. CardiAQ’s chordal-sparing approach, combined with its unique anchoring system, provides what can best be described as a ‘face-lift for the heart’ that may also help promote positive remodeling of the ventricle.”

About CardiAQ Valve Technologies

Privately held CardiAQ, headquartered in Irvine, Calif., has developed a proprietary system for Transcatheter Mitral Valve Implantation (TMVI). Through the combination of a unique anchoring mechanism and a novel delivery catheter, physicians will be able to accurately and securely implant a new mitral valve within a beating heart, thus avoiding open-heart surgery. The CardiAQ procedure is designed to be performed in a cardiac catheterization laboratory or hybrid operating room. Ultimately the procedure will be similar to angioplasty or stenting, resulting in less trauma to the patient and substantial potential cost-savings to the healthcare system.

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Caution: The CardiAQ™ Valve Technologies System for Transcatheter Mitral Valve Implantation is in the early phases of development. It will not be available in the USA for clinical trials until further notice and is NOT available for sale.