First Patient Treated in U.S. Randomized Trial of NeoChord's, Off-Pump, Minimally Invasive Repair for Degenerative Mitral Regurgitation

- *NeoChord reports initial use of DS1000 System in U.S. Pivotal Trial*
- *Results from initial enrollment success "very promising"*
- *Three U.S. Centers poised for initial trial enrollment*

ST. LOUIS PARK, Minn., Nov. 09, 2016 (GLOBE NEWSWIRE) -- NeoChord, Inc., a privately-held medical technology company leading the advancement of minimally invasive valve repair for degenerative mitral regurgitation (DMR), today announced the first use of its DS1000 System in the U.S. as it enrolled the first patient in the RECHORD Trial.

The RECHORD Trial is a prospective, multicenter, randomized FDA pivotal study intended to establish the safety and effectiveness of the DS1000 System as an alternative to standard surgical mitral valve repair. The study was approved to enroll up to 585 subjects at up to 20 U.S. centers. This study is the first trial of its kind to treat DMR patients that have ruptured or elongated chordae tendinae in a trans-apical, beating heart procedure.

David H. Adams, M.D., Cardiac Surgeon-in-Chief, Mount Sinai Health System, and his team successfully treated the first patient in the RECHORD Trial at The Mount Sinai Hospital in New York, NY. Dr. Adams, National Co-Principal Investigator of the trial, noted "the success that we observed with our first patient in the trial is very promising and is indicative of the strong clinical results observed in Europe in appropriately selected patients with degenerative mitral valve regurgitation."

"NeoChord's technology has the potential to empower surgeons to intervene earlier in the disease process than previously possible and before significant ventricular changes occur," said Co-Principal Investigator, Michael A. Borger, M.D., PhD, Professor and Director, Cardiovascular Institute, New York Presbyterian Hospital/Columbia University Medical Center in New York, NY. "Clinical evidence that demonstrates the benefit of earlier intervention would truly transform the surgical treatment paradigm for patients suffering from DMR."

In standard mitral valve repair procedures, patients are placed on cardiopulmonary bypass: the heart is arrested while the mitral valve is exposed and repaired. NeoChord's DS 1000 System technology allows for a truly minimally invasive procedure via a transapical puncture on a beating heart without the need for cardio-pulmonary bypass or aortic cross-clamping. As a result, the invasiveness of the repair procedure is significantly reduced. With the NeoChord procedure, the surgeon uses real-time echocardiographic feedback in the OR to precisely adjust the length of the newly placed chords and to reduce and/ or eliminate mitral valve regurgitation, while the heart is beating and functioning.

“We believe this innovative technology will create a new standard of care for patients suffering from degenerative mitral regurgitation in the United States," said David Chung, CEO and President of NeoChord. “With this first patient treatment milestone, we are continuing our commitment to bring the most advanced technology for clinicians and their patients affected by DMR to the U.S. We look forward to beginning initial enrollment at New York Presbyterian Hospital/Columbia University Medical Center with Dr. Borger and at PinnacleHealth in Harrisburg, PA, under the leadership of Dr. Mubashir Mumtaz, M.D., Chief of Cardiovascular and Thoracic Surgery; Surgical Director, Structural Heart Program.”

About NeoChord DS 1000 System

NeoChord DS1000 system is an off-pump, transapical surgical option for treating degenerative mitral valve disease proven to resolve mitral regurgitation and restore mitral valve function on a beating heart. The procedure is performed via a thoracotomy, unlike highly-invasive sternotomy based repair procedures. Using 2D and 3D echo guidance, the system is introduced through apex of the left ventricle and navigated to the mitral valve. The prolapsing segment of the dysfunctional mitral valve leaflet is grasped using the expandable jaws of the device. Leaflet capture is verified using a fiber optic monitor in real time. The suture is then deployed placing the artificial chordae on the free edge of the prolapsing segment of the mitral valve leaflet.

The level of mitral valve regurgitation is reduced by applying gradual tension to the artificial chordae and confirmed in real time via echocardiography. Once mitral valve regurgitation has been reduced to the desired level, the artificial chordae is secured to the apex of the heart.

About Degenerative Mitral Regurgitation (DMR)

Degenerative mitral regurgitation (DMR) is a progressive disease that can result in atrial fibrillation, congestive heart failure, and death when left untreated. It usually progresses slowly over time and patients may have no symptoms until complications occur. One of the earliest signs of mitral valve regurgitation is a heart murmur, which can be detected with a stethoscope. Symptoms may include shortness of breath upon exertion, fatigue when exercising, lightheadedness, cough when lying down, heart palpitations and swollen feet or ankles.

About NeoChord, Inc.

Founded in 2007 and based in St. Louis Park, Minnesota, NeoChord, Inc. is a privately held medical technology company leading the advancement of minimally invasive repair for DMR. NeoChord’s DS1000 system received CE market clearance in December 2012. NeoChord received IDE approval from the FDA for the US pivotal trial in May 2016. For more information, please visit the Company's website at www.neochord.com.

The NeoChord DS1000 System is CE marked and approved for sale in Europe.
CAUTION: Investigational Device Limited by Federal (United States) Law to Investigational Use.

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