

NeoChord Receives FDA Approval to begin Clinical Trial for Treatment of Degenerative Mitral Valve Regurgitation

Pivotal study will enroll up to 450 patients in a randomized trial of the DS1000 System.

May 13, 2016 11:00 AM Eastern Daylight Time

ST. LOUIS PARK, Minn.--([BUSINESS WIRE](#))--[NeoChord, Inc.](#) today announced that it has received Investigational Device Exemption (IDE) approval from the United States Food and Drug Administration (FDA) to begin a prospective, multicenter, randomized clinical trial for its Artificial Chordae Delivery System, DS1000.

“We are excited to begin our FDA approved pivotal trial at 20 U.S. mitral repair centers,” said Lori Adels, PhD, Vice President of Clinical, Regulatory and Quality at NeoChord. “This is the first U.S. clinical study of a trans-apical, beating heart procedure for replacement of ruptured or elongated chordae in patients with degenerative mitral valve regurgitation. The protocol was developed in consultation with the FDA and our Principal Investigators, David H. Adams, MD, Professor and Chairman, Department of Cardiovascular Surgery, Icahn School of Medicine at Mt. Sinai, New York, and Michael A. Borger, MD, PhD, Professor and Director, Cardiovascular Institute, New York Presbyterian/Columbia University Medical Center, New York, and is designed to establish the safety and efficacy of the DS1000 System as an alternative to standard surgical mitral valve repair.”

“IDE approval is a major milestone for NeoChord and its investors,” said David Chung, President and Chief Executive Officer at NeoChord. “This technology has demonstrated excellent outcomes in reducing mitral regurgitation in both clinical studies and commercial use outside the U.S., and we expect to demonstrate the same excellent results in our U.S. pivotal study. We look forward to making this transformational technology available to patients in the U.S.”

NeoChord received CE Marking approval for the DS1000 System in Dec. 2012 and began marketing the product in Q1, 2013. The company plans to expand the commercial availability of the DS1000 System to additional European markets throughout 2016 and 2017.

About NeoChord, Inc.

Based in St. Louis Park, Minn., NeoChord, Inc. is a privately held medical technology company leading the advancement of minimally invasive repair for degenerative mitral regurgitation (DMR). DMR is a progressive disease that can result in atrial fibrillation, congestive heart failure, and death when left untreated. NeoChord received CE

market clearance in December 2012 for the DS1000 System to treat DMR without the use of cardiopulmonary bypass. For more information, visit: 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

Contacts

NeoChord, Inc.

Bruce Van Deman, 952-698-7812

bvandeman@neochord.com