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SIX-MONTH DATA SUPPORTS FURTHER STUDY OF CLIP DEVICE FOR NON-SURGICAL MITRAL VALVE REPAIR

Less Invasive Cath Lab Procedure May Replace Major Open-Heart Surgery

(EVANSTON , ILL)--March 7, 2005—After the leaky mitral valves in their hearts were repaired non-surgically with a tiny, catheter-fed clip, nearly all – over 90 percent – of the patients whose mitral regurgitation (MR) was significantly reduced one month after receiving the clip maintained the reduction at six months. In addition, 75 percent of the patients who received the clip as part of a Phase I clinical trial are still surgery-free.

Mitral regurgitation is a debilitating condition that occurs when the mitral valve, which allows blood to move through the heart, fails to close properly.

“As we get more experience with this procedure, we’re seeing that our ability to control the MR is increasing and the time it takes to accomplish the repair is decreasing. With this device, we can provide a minimally invasive option for decreasing valve leakage without taking away the patient’s ability to have surgical valve repair in the future, if it’s needed,” says Principal Investigator Ted Feldman, MD, Director of the Cardiac Catheterization Lab at Evanston Hospital , flagship of the Evanston Northwestern Healthcare system.

Evalve, Inc. (Redwood City , CA) developed and manufactures the MitraClip™. The clinical trial is known as EVEREST I, **E**ndovascular **V**alve Edge-to-Edge **Re**pair **St**udy.

Dr. Feldman will present results of the EVEREST I trial today at 3 p.m. in Room 414-A at the American College of Cardiology's 54th Annual Scientific Session. Being held in Orlando , FL. The presentation, part of the Oral Contributions: Percutaneous Valve Procedures Session, is titled **Percutaneous Edge-to-Edge Mitral Valve Repair Using the Evalve Clip: Update on the EVEREST Phase I Clinical Trial.**

To date, a total of 27 patients with severe mitral regurgitation have been enrolled in the trial. Dr. Feldman performed the first U.S. procedure in Evanston Hospital 's Cardiac Catheterization Laboratory. Other U.S. investigators participating in the trial are: Hal Wasserman, MD, Columbia University Medical Center , New York ; William Gray, MD; Swedish Medical Center , Seattle ; Howard C. Herrmann, MD, University of Pennsylvania ; Peter C. Block, MD, Emory University Hospital , Atlanta ; and Patrick L. Whitlow, MD, Cleveland Clinic Foundation. Elyse Foster, MD, University of California , San Francisco , is Director of the Echocardiographic Core Lab.

"As a group, we have seen minimal rates of complications occur during the procedures. We've also seen that for the majority of patients who achieve good initial results, favorable results are sustained. The patients who did not receive optimal MR control with the clip were able to have routine, conventional mitral valve surgery," explains Dr. Feldman.

Moving forward

Nationwide, study centers will soon begin enrolling eligible patients in EVEREST II, a prospective, randomized, multi-center study that will compare the clip approach with open-heart valve surgery. For info rmation about study centers, visit www.evalveinc.com.

"The promising results that we've seen from EVEREST I justify moving this study forward," says Dr. Feldman. "This is one of several new devices that will help us improve faulty heart valves without the downtime of surgery," says Dr. Feldman.

About the procedure

Performed in a cardiac catheterization laboratory under general anesthesia, a catheter (a thin, flexible plastic tube) introduced through the skin in the thigh area, is guided from the femoral vein to the affected area of the valve in the heart. The clip is precisely steered into place and attached to the mitral valve, helping it to close properly. Once the clip is securely attached, the catheter is removed. The procedure is performed using echocardiography and fluoroscopy. Patients typically spend one or two nights in the hospital and return to normal activity within one week.

In chronic MR, blood leaks backward with each heartbeat, requiring the heart to work harder. It's a progressive disorder that affects approximately 4 million people in the United States . Approximately 250,000 patients develop significant mitral regurgitation annually in the U.S. Most of these patients eventually become so weakened by the

condition that they require open-heart surgery with cardiopulmonary bypass. Approximately 50,000 people a year have open, arrested-heart mitral valve surgery.

Last week, a study in the **New England Journal of Medicine** indicated that even patients with severe MR who do not yet have clinical symptoms obtain a significantly greater survival benefit from surgery compared to treatment with medication and delayed surgery. (Enriquez-Sarano, M**.,** *Quantitative Determinants of the Outcome of Asymptomatic Mitral Regurgitation*, 352:875-883)

About Evanston Northwestern Healthcare

Located in Chicago's northern suburbs, Evanston Northwestern Healthcare (ENH) is an integrated healthcare system that includes Evanston, Glenbrook and Highland Park Hospitals, ENH Medical Group (comprising 65 medical offices and facilities), ENH Home Services, ENH Research Institute and ENH Foundation.

*Through its affiliation with Northwestern University 's Feinberg School of Medicine, ENH supports extensive medical education and research programs. ENH is in the top 9 percent of all institutions that receive funding from the National Institutes of Health; among multi-specialty independent research hospitals it ranks 12*th *in the nation.*

ENH is also recognized as a leader for implementing technology and improving processes to advance the safety and quality of patient care. Its hospitals are the only ones in Illinois to have fully implemented the quality and safety practices recommended by the Leapfrog Group for Patient Safety. Hospitals and Health Networks magazine has named ENH one of the "Most Wired" healthcare organizations in the nation.*

**** 2004 Leapfrog Hospital Quality and Safety Survey***