Micro Interventional Devices, Inc.
Taking Aim at Structural Heart Disease

Micro Interventional Devices, Inc.™ Announces Continued Successful Enrollment in STTAR Trial

Three additional patients treated with 12F Percutaneous MIA™, Minimally Invasive Annuloplasty, Technology

Newtown, PA – November 29, 2018 – Micro Interventional Devices, Inc.™ (MID) announced the continued successful enrollment of patients in STTAR (the Study of Transcatheter Tricuspid Annular Repair) being conducted in Europe. MID's MIA™, Minimally Invasive Annuloplasty technology, is being studied for its safety and performance in the treatment of severe tricuspid regurgitation. MIA has now been successfully implanted percutaneously in four patients at three independent centers. The company is pleased to report that MIA is currently experiencing a 100% implant deployment success rate with no adverse events or complications reported or experienced.

The image-guided procedure relies on fluoroscopy and 3D echocardiography to accurately place the PolyCor™ anchors of the MIA implant on the annulus of the tricuspid valve. MIA's proprietary PolyCor anchoring technology enables the percutaneous bicuspidization of the tricuspid valve, replicating results of an open surgical bicuspidization procedure. Very notable differences exist between surgery and the percutaneous MIA approach. For instance, MIA is delivered under conscious sedation and therefore is performed on a beating heart obviating the need for cardio pulmonary bypass. As a result, the use of MIA greatly reduces recovery time, blood loss and hospital stay.

Patients have now been successfully treated at three centers in Europe. They are the Vilnius University Hospital Santariskiu Clinic in Vilnius, Lithuania (Profs. Aidietis and Rucinskas); The Lithuanian University of Health Sciences, Kaunas Clinic in Kaunas, Lithuania (Prof. Benetis); and The Semmelweis University Heart and Vascular Center in Budapest, Hungary (Prof. Merkely and Dr. Molnar). Proctoring the first three cases were renowned structural heart repair experts, Mathew Williams, MD, Director of the Heart Valve Center, and Alan Vainrib, MD, Cardiologist and Echocardiography Specialist, both from NYU Langone Health.

Enrolled patients ranged in age from 61 to 85 years old and suffered from severe tricuspid regurgitation. Severe tricuspid regurgitation can lead to numerous clinical complications including: fatigue, shortness of breath, and other heart failure symptoms. Successful implantation of MIA was achieved, in each case, using the 12F MIA delivery catheter used to deploy a series of PolyCor anchors into the posterior annulus of the tricuspid valve. Significant reductions in tricuspid regurgitation of 2 or more grades from severe/torrential to

moderate/mild or mild with annular area reductions of as much as 48% were reported.

The technology was utilized to treat a wide range of etiologies including a patient with a pacemaker lead who was successfully treated resulting in a 45% reduction in annular area and a 2 grade reduction in regurgitation. Mean procedural time for the first four patients was 2 hours and 13 minutes with the shortest time being 1 hour and 10 minutes, suggesting a rapid learning curve.

MID continues to expand its study sites in Europe through proctoring and consulting with world renowned interventionalists including Professor Antonio Colombo, MD, General Coordinator Cardiac Cath. Labs, Gruppo GVM, Director Cath Lab, Columbus Hospital, Milan, Italy and Professor Joachim Schofer, MD, Chief of Cardiology at the Albertinan Medical Center in Hamburg, Germany.

“The outcomes of these procedures are really impressive, with significant reductions in tricuspid regurgitation and annular dimensions,” Professor Schofer said. “The MIA technology appears to be easy to deploy and the implant can be customized to the patient’s anatomy.”

“The key to this technology is the unique PolyCor anchor that appears to have advantages over other anchoring approaches,” said Professor Colombo. “The company has made significant progress and is on the right track.”

Forty patients will be enrolled in the STTAR multicenter clinical study, leading to a CE Mark approval. The STTAR study will be expanded to the United States in 2019. MID has identified numerous centers of excellence that have expressed significant interest in participating in STTAR.

“MID set out to develop a technology that is simple, safe and secure,” said Michael Whitman, President and CEO. “That was over 7 years ago. The early outcomes we are experiencing with MIA suggest that we have achieved this objective. Clearly we are extremely pleased with these results and are very thankful for the guidance and support of our talented interventional and surgeon advisors.”

There are an estimated 1.1 million patients suffering from tricuspid regurgitation in the US alone. MID’s focus is on this large patient population, with the intent of improving their quality of life.

About Micro Interventional Devices, Inc. (MID):

MID is a world leader in the percutaneous treatment of structural heart disease.

MIA utilizes proprietary, compliant PolyCor™ anchors, the world's first low mass polymeric implant designed to comply with normal physiological valvular function. The MIA implant is engineered to plicate and comply with cardiac tissue once deployed.

Mathew Williams, MD, Director of the Heart Valve Center at NYU Langone Health, reports disclosures with MID.

Company Contact:
Micro Interventional Devices, Inc.
Katherine Whitman
Director of Marketing
215 600 1270
info@microinterventional.com
www.microinterventional.com