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

Micro Interventional Devices, Inc.™ Announces Submission of CE Mark Technical Documentation for the MIA-T™ Percutaneous Tricuspid Annuloplasty System

Filing includes one year-follow up data from the STTAR Clinical Study.

Newtown, PA – January 28, 2021 – Micro Interventional Devices, Inc.™ (MID)

MID announced today that it has submitted the required technical documentation for CE Mark approval for its MIA-T™ Percutaneous Tricuspid Annuloplasty System for tricuspid valve repair to its Notified Body. The receipt of a CE Mark would allow MID to commercialize MIA-T in the European Union in countries governed by the European Medical Device Regulations (MDR). MID is anticipating an approval in 2021. This will enable a treatment option for millions of patients currently at too high a risk to be treated with the standard of care, open surgical repair with cardiopulmonary bypass.

The MIA-T System was clinically evaluated in STTAR, the Study of Transcatheter Tricuspid Annular Repair, conducted at six European hospitals. The image-guided procedure relies on fluoroscopy and 3D echocardiography to treat patients suffering from tricuspid regurgitation while the heart is beating, obviating the need for cardiopulmonary bypass. This less invasive treatment option would dramatically increase the number of patients who are able to receive treatment for this disease.

“CE Mark submission is a major milestone for MID,” said Michael Whitman, President and CEO. “The receipt of a CE Mark approval will allow MID to offer a safe and effective therapeutic option for patients who are poorly served by current medical and surgical options and sets the stage for the next significant phase in this company’s growth. It is also worthy to note that this filling is being submitted under the current EU Medical Device Regulation (MDR) 2017/745.”

Thirty-one patients have been treated with the MIA-T technology to date. The initial data indicate that significant reductions in annular dimensions and tricuspid regurgitation achieved acutely with MIA-T are durable at one year follow-up. The data also indicate significant improvements in Quality of Life for patients treated with the MIA-T system. There were no device or procedure-related deaths, strokes or myocardial infarctions reported for any patient throughout the 12-month follow-up period. The device has not been approved for commercial use at this time.

"The clinical data from STTAR demonstrate the safety and performance of the MIA-T system," said Willard Hennemann, PhD, MID's Chief Science Officer. "The encouraging clinical results, short procedure times and short learning curve demonstrated during the study suggest that the MIA-T system has the potential to readily become adopted as standard of care therapy for the treatment of moderate-severe tricuspid regurgitation upon CE Mark approval."

Additionally, MID continues to work closely with the FDA on its IDE submission for the STTAR - US clinical trial. This will be a multi-center trial conducted at 30 sites in the United States. MID hopes to gain approval from the Agency to begin its US Trial for PMA approval later this year.

About Micro Interventional Devices, Inc. (MID):

MID is a world leader in Transcatheter Cardiac Repair (TCR) utilizing its proprietary percutaneous compliant fixation technology that emulates open surgical procedures addressing diseases of the heart.

MIA-T utilizes proprietary, compliant PolyCor™ anchors, the world's first low mass polymeric implant designed to comply with normal physiological valvular function. The MIA-T implant is engineered to plicate and comply with cardiac tissue once deployed.

MID is a privately held medical device company developing minimally invasive solutions for structural heart disease. MID's primary focus is repairing the tricuspid and mitral valves while the heart is beating, eliminating the need for cardiopulmonary bypass surgery.

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