

## Micro Interventional Devices Receives FDA Approval of the STTAR-US IDE Pivotal Trial for its MIA™-T Percutaneous Tricuspid Annuloplasty System

Newtown, Pennsylvania, October 15, 2025 – <u>Micro Interventional Devices (MID)</u>, a pioneering company in Transcatheter Tricuspid Valve Repair (TTVr) developing MIA-T (Minimally Invasive Annuloplasty – Tricuspid), a novel technology for the treatment of tricuspid annular disease, today announced that the U.S. Food & Drug Administration (FDA) has approved the company's technology for Investigational Device Exemption (IDE) use, which allows the pivotal clinical trial to begin at notable U.S. hospitals. MID has been working closely with the FDA since receiving our Breakthrough Technology Designation.

The STTAR-US pivotal trial will provide an annular treatment utilizing MID's proprietary, polymeric PolyCor<sup>TM</sup> anchors developed specifically for use in cardiac tissue. These anchors are deployed into the tricuspid annulus via 12F delivery catheters. The technology is designed to treat functional tricuspid valve disease by reducing annular area, minimizing Tricuspid Regurgitation (TR), and encouraging natural healing.

The STTAR-US Steering Committee is composed of thought leaders in the structural heart field. The trial will be led by two distinguished cardiologists as Principal Investigators, Bassem Chehab, MD who serves as an Associate Professor of Medicine at the University of Kansas and is the Director of Structural Cardiology, Clinical Cardiology and Research at Ascension Health, Wichita, Kansas and Saibal Kar, MD who serves as the Program Director Cardiovascular Disease Fellowship, Los Robles Regional Medical Center, Thousand Oaks, California and the National Physician Director, Interventional Cardiology HCA Healthcare US.

Significant unmet clinical needs exist in the treatment of TR with 1.6 million people in the US alone suffering from TR and only a small percentage of those patients are eligible to receive surgical treatment. MIA-T aims to address a large, untreated patient population and is unique among tricuspid repair and replacement technologies in its versatility and capability to treat patients who are ineligible for surgical or TEER procedures.

"This approval marks a critical milestone in the development of MIA-T. As one of the first percutaneous annular repair devices, we believe MIA-T will play a significant role in the emerging TTVr market. The global market is projected to exceed \$3 billion annually by 2027, with rapid growth expected as minimally invasive options advance and adoption increases," said Michael Whitman, Chief Executive Officer of Micro Interventional Devices. "With a rapidly growing global market and no established percutaneous standard of care for treating tricuspid regurgitation, we believe MIA-T has

the potential to deliver both meaningful patient outcomes and significant value for our stakeholders."

## **About Micro Interventional Devices, Inc. (MID):**

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

MIA-T utilizes proprietary, compliant PolyCor<sup>™</sup> 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.

For more information please contact Christopher Whitman, Vice President of Finance.

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