AtriCure Announces the First Patient Treated in the HEAL-IST Clinical Trial

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Trial will evaluate the safety and effectiveness of AtriCure's Isolator® Synergy ™Clamp in conjunction with endocardial catheter ablation for the treatment of Inappropriate Sinus Tachycardia

MASON, Ohio--(BUSINESS WIRE)--Jun. 7, 2022-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatments and therapies for atrial fibrillation (Afib), left atrial appendage (LAA) management and post-operative pain management, today announced that the first patient was treated in the HEAL-IST™ trial (NCT 05280093). The first patient was treated by DrsMark LaMeir and Carlo de Asmundis at University Hospital Brussels. The HEAL-IST trial will evaluate the safety and effectiveness of AtriCure's Isolator ® Synergy™ Clamp for the treatment of drug-refractory patients diagnosed with Inappropriate Sinus Tachycardia (IST). Sinus tachycardia normally occurs when the body sends out signals to make the heart beat faster, such as when some people experience stress or physical exertion during exercise. When it happens unexpectedly or for no easily identifiable reason, the condition is called Inappropriate Sinus Tachycardia.

The HEAL-IST trial is a prospective, multicenter, single-arm study of 142 patients at up to 40 centers in the United States and Europe. The therapy being studied involves a hybrid epicardial and endocardial procedure, during which a cardiac surgeon and an electrophysiologist work together to create lesions on the right side of the heart. The primary effectiveness endpoint is freedom from IST, defined as having a mean heart rate of less than 90 beats per minute, or at least a 15% reduction in mean heart rate compared to a pre-operative baseline. The primary safety endpoint is procedure or device related adverse events through 30 days after the surgery is completed.

"Symptomatic IST is a serious arrhythmia that dramatically decreases the quality of life in predominantly younger adults, and more specifically, young women," said Dr. LaMeir, Professor and Head of Cardiac Surgery at University Hospital Brussels, and co-principal investigator in the HEAL-IST trial. "Further, since current antiarrhythmic drug treatment has limited long-term effect, and societal guidelines do not advise sinus node ablation or modulation, this landmark study of sinus node sparing hybrid ablation has the potential to establish a standard of care for these patients."

"We believe that cardiac surgeons and electrophysiologists working together is a safe and highly effective way to treat complex arrhythmias," said Michael Carrel, President and Chief Executive Officer of AtriCure. "The HEAL-IST trial is an example of AtriCure's commitment to, and leadership in improving the lives of patients. The therapy has the potential to significantly expand our addressable markets."

"IST is a common disease that is often under or mis-diagnosed," said Dr. de Asmundis, Professor and Director of Heart Rhythm Management at University Hospital Brussels, and co-principal investigator in the trial. "There are currently no approved treatments for this disease. The HEAL-IST trial, which is based on years of research from our clinic, has a chance to prove how successful this procedure can be."

About AtriCure

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 33 million people worldwide. Electrophysiologists and cardiothoracic surgeons around the globe use AtriCure technologies for the treatment of Afib and reduction of Afib related complications. AtriCure's Isolator ® Synergy™ Ablation System is the first medical device to receive FDA approval for the treatment of persistent Afib. AtriCure's AtriClip ® Left Atrial Appendage Exclusion System products are the most widely sold LAA management devices worldwide. AtriCure's Hybrid AF™ Therapy is a minimally invasive procedure that provides a lasting solution for long-standing persistent Afib patients. AtriCure's cryoICE cryoSPHERE® probe is cleared for temporary ablation of peripheral nerves to block pain, providing pain relief in cardiac and thoracic procedures. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

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