Acutus Medical® Announces First Patient Procedure in Pivotal Atrial Fibrillation Trial…

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Acutus Medical® Announces First Patient Procedure in Pivotal Atrial Fibrillation Trial (UNCOVER-AF) and Introduction of the World's First ElectroFunctional™ Procedure

- European and Canadian Clinical Study Evaluates AcQMap® High Resolution Imaging and Mapping System -

CARLSBAD, CA—October 26, 2016— Acutus Medical, an electrophysiology company committed to transforming how electrophysiologists (EPs) image, diagnose and treat complex arrhythmias, today announced the completion of the first patient procedure in the "Utilizing Novel Dipole Density Capabilities to Objectively Visualize the Etiology of Rhythms in Atrial Fibrillation" (UNCOVER-AF) clinical study. The study will evaluate the incidence of device and procedure-related safety, effectiveness and efficiency using the AcQMap High Resolution Imaging and Mapping System to guide ablation in persistent atrial fibrillation (AF) patients.
Acutus Medical received CE Mark approval for the AcQMap System and AcQMap Catheter in May 2016. Patients are currently being enrolled in the UNCOVER-AF clinical study at electrophysiology (EP) centers of excellence throughout Europe and Canada. The first procedure was successfully completed by Andrew Grace, MD, PhD and Sharad Agarwal, MD, at Papworth Hospital in Cambridge, United Kingdom.

The AcQMap System ushers in a new standard of care allowing EPs who until now, have never been able to fully visualize all the electrical mechanisms combined with the functional mechanism of AF," said Dr. Andrew Grace. "Being able to truly see each heart beat in real-time, with CT quality imaging and full-chamber electrical-conduction maps has the potential to more accurately inform treatment decisions and improve patient outcomes.

Persistent AF is a complex, heterogeneous, patient-specific arrhythmia with limited treatment options that consist of oral medications, electric shocks to convert the heart rhythm and empiric ablation strategies. Outcomes, regardless of treatment options, have been disappointing. The AcQMap System combines a real-time CT quality anatomy with an ability to map the electrical-conduction of each heartbeat to precisely visualize electric sources across the entire chamber thus enabling the pinpointing of sites crucial for driving and maintaining AF. Following guided treatment, the next heartbeat can be remapped in seconds to confirm successful ablation and define additional treatment, if needed. This progressive treatment strategy of mapping, ablating and remapping to systematically break down the complexity of the AF frequently leads to spontaneous termination with conversion to sinus rhythm.

The initiation of this study marks another major milestone for the company and furthers our mission to improve the lives of patients living with persistent AF," said Randy Werneth, president and chief executive officer of Acutus. "We believe the clinical outcomes from UNCOVER-AF will confirm what we set out to achieve with this system—to allow EPs to obtain real-time images of the heart chamber and identify the true source of the arrhythmia, thus leading to improved patient outcomes and improved quality of life.

Early clinical results using the AcQMap System have demonstrated accurate left atrial reconstruction when compared with CT/MRI and dipole density mapping offering a significantly higher resolution than voltage-based mapping.

About AcQMap High Resolution Imaging and Mapping System

AcQMap High Resolution Imaging and Mapping System from Acutus Medical is a new and first of its kind of technology, creating the ability for EPs to perform a new procedure called "ElectroFunctional". This new procedure is intended to enable physicians to see in real-time the functioning heart in combination with the true nature of electrical conduction, in terms of the actual electric sources called "dipole density". The AcQMap System reveals the electrical conduction of the whole heart chamber in extraordinarily high resolution giving EPs unprecedented visualization to identify sites crucial for driving and maintaining AF, enabling discrete ablation of only those locations that contribute to the patient-specific disorder. The outcome of a successful ElectroFunctional procedure may dramatically improve the likelihood of single-procedure success, preserve healthy tissue and improve cardiac function. While previous voltage based electroanatomic technologies have shown static, geometric representations of the heart, the AcQMap System simultaneously uses intra chamber ultrasound and dipole density mapping to display highly accurate real-time physical mechanics and electrical activity with the ability to remap in seconds to confirm successful substrate modification.

About Acutus Medical
Acutus Medical is dedicated to partnering with the EP community to provide a full range of ElectroFunctional solutions from diagnosis through treatment. Acutus Medical is a privately held company located in Carlsbad, CA. To learn more, visit https://www.acutusmedical.com
The AcQMap High Resolution Imaging and Mapping System is not available for sale in the United States