



Acutus Medical Initiates First IDE Therapy Trial with the AcQBlate® FORCE Sensing Ablation System

April 5, 2021

CARLSBAD, Calif., April 05, 2021 (GLOBE NEWSWIRE) -- Acutus Medical (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced initial US enrollments in the company's AcQForce™ Flutter Investigational Device Exemption (IDE) clinical trial. This trial is expected to enroll up to 150 subjects in leading centers globally and will evaluate the safety and efficacy of the AcQBlate FORCE sensing ablation catheter and system in the treatment of Right Atrial Typical Flutter. In the US, Right Atrial Typical Flutter ablation procedures currently account for approximately 30% of cardiac ablations and are expected to reach 200,000 annually by 2025¹.

In contrast to the most contemporary ablation systems, AcQBlate FORCE can operate both in a stand-alone manner or in conjunction with a compatible 3D mapping system. The AcQBlate FORCE sensing ablation system is comprised of Acutus' AcQBlate FORCE catheter and Qubic Force module that seamlessly integrates an RF generator and irrigation pump. The complete AcQBlate FORCE sensing ablation catheter and system, which received full CE Mark in late 2020, is now commercially available in Europe through our Acutus direct organization and our partner BIOTRONIK.

Designed specifically to provide consistent, effective therapeutic solutions during cardiac ablation procedures, the AcQBlate FORCE system shows physicians, in real-time, how much contact force is being applied to the heart during ablations. Studies have shown the utility of real-time contact force information in helping physicians guide safe and effective therapy, which may improve patient outcomes².

"The AcQBlate FORCE sensing ablation catheter provides stable contact force readings with low fluid irrigation requirements. It displayed both easy maneuverability and excellent stability during atrial ablation. I look forward to further evaluating this system and believe this technology has the potential to improve patient outcomes," said Dr. Gery Tomassoni of Baptist Health Medical Group in Lexington, Ky., who performed the first case in the trial.

Dr. Sean Beinart of Adventist Healthcare White Oak Medical Center in Silver Springs, Md. further commented, "the system was very easy for our lab staff to set up, and we were able to complete the case without changing our existing workflow. As the incidence of atrial arrhythmias increases, we continue to look for safe, effective and efficient treatment options for patients. The AcQBlate FORCE sensing ablation catheter incorporates a gold-tipped electrode that is designed for efficient energy delivery and effective lesion creation in less time."

"This trial represents our initial entry into the United States with a therapeutic technology for the treatment of atrial arrhythmias," said Vince Burgess, CEO of Acutus Medical. "The gold-tipped AcQBlate FORCE catheter is a state-of-the-art ablation device that is paired with our laser-based contact force console and further integrated with the smallest and most modern RF generator and pump available. As we have experienced in our European centers during our initial market release, when used in concert with our novel AcQMap 3D mapping system we are seeing highly efficient workflow and operational efficiency. We look forward to offering the benefits of a comprehensive, force sensing ablation system to electrophysiologists and patients in the United States once we complete clinical trials and gain regulatory approval."

Enrollment for the AcQForce Flutter trial is ongoing, and the company is actively working with selected sites to initiate cases under the IDE. For more information on this trial, please see NCT04658940 on <https://www.clinicaltrials.gov>. AcQBlate FORCE Sensing Catheter is limited by US Federal Law to investigational use.

References

1. Erik J. Bracciodieta, Electrophysiology Mapping and Ablation Devices, Market Insights, US. Decision Resources Group M360EP0059, June 2019.
2. Ariyaratna N. et al., Role of Contact Force Sensing in Catheter Ablation of Cardiac Arrhythmias: Evolution or History Repeating Itself? JACC: Clinical Electrophysiology (2018); 707-723

About Acutus Medical

Acutus Medical is an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Acutus is committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more efficiently and effectively. Through internal product development, acquisitions and global partnerships, Acutus has established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products that provide its customers with a complete solution for

AcQBlate FORCE Sensing Ablation System



A complete ablation system which includes the smallest footprint of any RF Generator and is comprised of four components: Qubic RF controller, Qubic Force Module, Qubic RF Generator and Qiona Irrigation pump.

AcQBlate FORCE Sensing Ablation Catheter



AcQBlate FORCE: the first and only force sensing ablation catheter with a gold-tip electrode.

catheter-based treatment of cardiac arrhythmias. Founded in 2011, Acutus is based in Carlsbad, California.

Follow Acutus Medical on:

- Twitter: [@AcutusMedical](#)
- LinkedIn: www.linkedin.com/company/acutus-medical-inc/
- Facebook: [@AcutusMedical](#)

Media Contact

Holly Windler
619-929-1275
holly.windler@acutus.com

Investor Contact

Caroline Corner
415-202-5678
caroline.corner@westwicke.com

Photos accompanying this announcement are available at

<https://www.globenewswire.com/NewsRoom/AttachmentNg/6c455e7c-6377-4f65-b55d-b51acd15a2ea>

<https://www.globenewswire.com/NewsRoom/AttachmentNg/3f011ba9-59e5-430c-a559-b9d66b6822b8>