# Acutus Medical Announces Submission of Premarket Approval Application for AcQBlate Force Sensing Ablation Catheter & System

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CARLSBAD, Calif., Oct. 18, 2022 (GLOBE NEWSWIRE) -- Acutus Medical, Inc. (“Acutus” or the “Company”) (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced submission of pivotal clinical data from the AcQForce Flutter trial designed to gain marketing approval from the U.S. Food & Drug Administration (FDA) for the AcQBlate Force Sensing Ablation Catheter and System (AcQBlate FORCE). Catheter ablation procedures to treat right atrial flutter account for approximately 30% of ablations in the US and are expected to reach 200,000 by 2025[1].

“Submission of the AcQBlate FORCE PMA application represents a major milestone in our evolution as we expand our portfolio in the United States to include an integrated mapping and therapy system,” said David Roman, President & CEO of Acutus Medical. “The demonstrated performance of the AcQBlate FORCE in the US IDE study, along with strong commercial adoption in Europe through our direct sales force and distribution partner, Biotronik, underscores our confidence in our growth strategy for 2023 and beyond.”

The AcQForce Flutter trial was a prospective, multicenter, non-randomized study approved under an FDA Investigational Device Exemption (IDE) and conducted in Right Atrial Typical Flutter patients presenting for a de novo percutaneous cardiac ablation of the cavo-tricuspid isthmus (CTI). The trial enrolled 110 patients at 21 sites globally and was designed to evaluate the safety and efficacy of the AcQBlate FORCE sensing ablation catheter and system in the treatment of right atrial typical flutter[2]. Primary endpoints were acute procedural success defined as bidirectional CTI block, and freedom from serious adverse events seven days post procedure.

The AcQBlate Force Sensing Ablation Catheter and System includes AcQBlate FORCE – the only force-sensing ablation catheter with a gold tip electrode, Qubic RF – the smallest radio frequency (RF) ablation generator in its class, the Qiona irrigation pump, and the Qubic Force Module. In the AcQForce Flutter trial, patients undergoing treatment with the AcQBlate Force Sensing System received successful therapy with clinically meaningful results. The primary efficacy endpoint was achieved, and the study observed no serious adverse events.

The AcQForce Flutter Clinical Study Report (“CSR”) was submitted to FDA as part of the Company’s modular PMA submission strategy. The CSR provides comprehensive safety and efficacy results and a detailed analysis of the full cohort of patients in the AcQForce Flutter trial. The Company intends to present full data from the AcQForce Flutter study at the AF Symposium in February 2023.

Designed specifically to provide consistent, effective therapeutic delivery during cardiac ablation procedures, the AcQBlate FORCE system has a unique gold tip electrode, low flow irrigation, and contact force sensing capabilities. The irrigated gold tip electrode has 4x thermal conductivity compared to platinum catheters, which allows for significantly more energy delivery at a lower temperature and requires less saline flow[3]. Contact force show physicians, in real-time, how much force is being applied to the heart from the catheter tip 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 outcomes[1].

**References**


1. Electrophysiology Mapping and Ablation Devices, Market Insights, US. Decision Resources Group M360EP0062, June 2020
2. 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.
3. Linhart M. et al., Superiority of Gold Compared to Platinum Tip Irrigated Catheter Ablation of the Pulmonary Veins and the Cavotricuspid Isthmus: A Randomized Study Comparing Tip Temperatures and Cooling Flow Requirements. J Cardiovasc Electrophysiol. 2012 Jul; 23(7): 717–21


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

**Caution Regarding Forward-Looking Statements**
This press release includes statements that may constitute “forward-looking” statements, usually containing the words “believe,” “estimate,” “project,” “expect” or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, the Company’s ability to continue to manage expenses and cash burn rate at sustainable levels, continued acceptance of its products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase the Company’s systems and the timing of such purchases, competitive factors, changes resulting from healthcare policy in the United States and globally, including changes in government reimbursement of procedures, dependence upon third-party vendors and distributors, timing of regulatory approvals, the impact of the coronavirus (COVID-19) pandemic and Acutus' response to it, and other risks discussed in the Company’s periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, Acutus undertakes no obligation to update these statements for revisions or

changes after the date of this release, except as required by law.

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