Late-Breaking ACQFORCE FLUTTER Trial Meets Primary Endpoint for Safety and Efficacy with the First Gold-Tipped Contact Force Sensing Ablation Catheter

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The AcQBlate Force Sensing Ablation Catheter and System demonstrated 94% acute success with no serious adverse events and significantly less ablation time

CARLSBAD, Calif., Feb. 06, 2023 (GLOBE NEWSWIRE) -- Acutus Medical, Inc. (“Acutus”) (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced results from the AcQForce Flutter Study “AcQForce Flutter: Force Sensing RF Ablation with Low Flow Gold Tip Catheter for Typical Flutter”. Results were presented during the Late-Breaking Clinical Trials and First Report Investigations session at the AF Symposium in Boston.

“We are encouraged by the positive results of the AcQForce Flutter Study and our ability to help physicians deliver more efficient ablation therapy,” said David Roman, President & CEO of Acutus Medical. “The study is a critical component of our PMA submission to expand our portfolio in the United States to include a fully integrated mapping and therapy solution, and these data reinforce our conviction that AcQBlate will be an important driver of our growth plans in 2023 and over the long-term.”

AcQForce Flutter Study 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. Acute success was achieved in 94% of patients and there were no serious adverse events. Ablation time was 13.5 ± 10.0 minutes, 33% less than comparative systems (20.0 ± 14.0 min in BLOCK-CTI) [1,2]. AcQBlate required only 250.4 ± 172.2 ml of irrigation during the procedure, significantly less than comparative systems (699 ± 386 min in BLOCK-CTI)[1,2]. Overall, the study demonstrated comparable outcomes to historic controls with significantly shorter ablation time and lower fluid volumes.

“AcQBlate’s novel gold tip ablation catheter performed extremely well during the clinical IDE atrial flutter cases. Short procedural times, stable contact force, and less irrigation volume contributed to efficient and safe ablation procedures. The delivery of low irrigation volumes during ablation should result in better fluid management and post-procedure patient recovery,” said Dr. Gery Tomassoni, Electrophysiologist at Baptist Health Lexington, KY and the principal investigator of the study.

The AcQBlate FORCE sensing ablation catheter and system, which received CE Mark in 2020, is commercially available in Europe. The AcQBlate FORCE sensing ablation catheter was designed to provide consistent, effective therapeutic delivery during cardiac ablation procedures. Its unique gold tip electrode has 4x the thermal conductivity of platinum catheters, which allows for significantly more energy delivery at a lower temperature and low irrigation flow rates[3]. Recent studies completed with the catheter in Europe have demonstrated excellent performance in a variety of clinical cases with significant reductions in ablation time and without procedural complications[4].

Acutus submitted its premarket approval application for the AcQBlate FORCE sensing ablation catheter and system on October 3, 2022 and is currently under review.

To learn more about Acutus Medical’s complete portfolio of diagnostic, access and therapy products, please visit https://acutusmedical.com.

References

1.Tomassoni, et al. AcQForce Flutter Trial Clinical Results: Force Sensing RF Ablation with Low Flow Gold Tip Catheter for Typical Flutter. Presented at AF Symposium (Late-Breaking Clinical Trials and First Report Investigations). Boston, MA. Feb 3rd, 2023
2. SSED for The Blazer Open-Irrigated Ablation Catheter (P150005) which was supported by BLOCK-CTI (NCT01253200). Approval Order dated February 24 2016.
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
4. Parwani, et al. First clinical experience of high-power ablation of atrial fibrillation with a novel contact force-sensing gold-tip catheter. Cardiology Journal 2022 Sept; 29(5): 759–765

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

About AF Symposium

The AF Symposium is an intensive three-day symposium that brings together the world's leading medical scientists to share, in a highly interactive environment, the most recent advances in the field of atrial fibrillation. The AF Symposium was initiated in 1995 in response to the growing epidemic of atrial fibrillation. Over the past 28 years, the meeting has become a major scientific forum at which health care professionals have a unique opportunity to learn about advances in research and therapeutics directly from many of the most eminent investigators in the field.

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