

Galaxy Medical Enrolls First Patients In SPACE-AF Study

SAN CARLOS, California, September 20, 2021 – Galaxy Medical announced today the initiation of the SPACE-AF study with enrollment of the first two patients at Southlake Regional Health Centre in Newmarket, Canada. In the study, the CENTAURI Pulsed Electric Field (PEF) ablation system will be used to ablate both the pulmonary veins and posterior walls in patients with persistent atrial fibrillation (AF). Recently, Galaxy has also enrolled additional subjects in the ECLIPSE-AF study using the CARTO mapping system and CE-Marked catheters manufactured by Biosense Webster, achieving CENTAURI compatibility with the three market leading cardiac mapping systems and their associated catheters.

Atul Verma, MD, Head of the Heart Rhythm program at Southlake Regional Health Centre and Primary Investigator in the SPACE-AF study commented: “We are thrilled to launch the first study of focal ablation through a solid tip catheter with PEF to treat both the pulmonary veins and atrial targets beyond the pulmonary veins including the left atrial posterior wall. Patients with persistent atrial fibrillation often require electrical isolation beyond simple pulmonary vein isolation and for years we have been seeking a safe, predictable, and effective energy source to do so. In our first two cases using the CENTAURI focal PEF approach, I customized the lesion sets to each patient in our installed CARTO system. The procedures were nearly identical to our standard radiofrequency ablation cases, but with the added confidence of PEF as compared to thermal modalities. We look forward to reporting on the procedural safety and long-term efficacy results of this study.”

Expanding on the ECLIPSE-AF trial in Europe, SPACE-AF will enroll up to 30 patients in Canada with persistent atrial fibrillation who require treatment beyond pulmonary vein isolation. After assessing safety and acute efficacy of pulmonary vein and posterior wall focal ablation with the CENTAURI System and approved catheters and mapping systems, patients will be followed to determine efficacy at 6 and 12 months. Presence of acute microbubbles will be graded during the procedure via intracardiac echo (ICE) imaging and cranial MRIs will evaluate for emboli.

“CENTAURI was designed to democratize PEF technology, allowing electrophysiologists to use any catheter and mapping system to create any lesion set. The launch of SPACE-AF validates this approach as Dr. Verma delivered PEF through a SMARTTOUCH catheter in CARTO to create a complex lesion set customized to the patient’s anatomy, which could not be achieved by any one single shot catheter. Taking an open system approach, it is a major milestone to achieve compatibility with CARTO, Ensite Precision, and RHYTHMIA HDx as we prepare for the commercial launch of the CENTAURI system in Europe. We look forward to releasing more data soon on microbubble reduction and the long term outcomes from our WAVE1 optimized dosing cohort,” said Jonathan Waldstreicher, M.D., CEO of Galaxy Medical.

CENTAURI is an investigational device and not commercially available.

ABOUT GALAXY MEDICAL

Galaxy Medical (www.galaxymed.com) is a privately held medical device company based in San Carlos, CA, that is dedicated to developing therapies to treat patients with cardiac arrhythmias. Formed by ATP, a leader in life sciences venture capital, Galaxy is building a portfolio of technologies to address the needs of cardiac electrophysiologists.

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