

Galaxy Medical Releases ECLIPSE-AF Remapping Data at Stanford Biodesign Retreat and Update on System Interoperability

SAN CARLOS, California, July 28, 2021 – Galaxy Medical announced today that the ECLIPSE-AF 90-day remapping data, presented at the Stanford BioDesign New Arrhythmia Technologies retreat, demonstrated durable lesions and chronic pulmonary vein isolation (PVI). Also, the company has recently treated patients in the same study using CE-Marked catheters and mapping systems from Boston Scientific, Biosense Webster and Abbott.

The ECLIPSE-AF Trial launched in September 2020 to study the acute safety of Galaxy's flagship CENTAURI™ system, which uses Pulsed Electric Field (PEF) technology to treat cardiac arrhythmias. Results for the first fifty patients who reached the 90-day remapping procedure were presented by Dr. Ante Anic, Electrophysiology Laboratory Director at University Clinical Hospital in Split, Croatia, and primary investigator of the study. Acute PVI was achieved in all 50 patients, with first pass isolation in 90% of pulmonary veins (PVs). In the 49 patients that were remapped, the per-PV isolation rate improved from 47% to 84% as PEF dose increased from the first to the third cohorts. Subsequent enrollments have been performed with an optimized treatment intensity and workflow. Gaseous emboli have not been observed on any activation and neurocognitive scores have remained unchanged from baseline. Twelve patients underwent pre-and post-procedure cranial MRI, and no cerebral lesions were detected with DWI and FLAIR.

"These initial results are very promising as compared to the current standard of care and as we continue to add more patients with optimized parameters, I am confident that the chronic isolation rates will remain high. Focal ablation is a cornerstone of my practice and with the efficacy data presented, I look forward to shifting my practice from radiofrequency to PEF, especially considering CENTAURI's ability to integrate with market leading mapping systems" said Dr. Anic .

Dr. Shephal Doshi, Director of Electrophysiology at St. Johns Health Center and the Pacific Heart Institute Santa Monica, CA commented: "This data is exciting, especially since they are achieved with the focal catheters that we have much experience and comfort with. With the promise of PEF technology, we look forward to demonstrating the utility of focal PEF for various arrhythmias." Dr. Doshi will be the National PI for Galaxy Medical's upcoming US IDE Trial.

"From the moment we conceived the CENTAURI System, our mission has been to democratize PEF technology, leaving the choice of the mapping system and catheter to the electrophysiologist. Having successfully completed procedures in ECLIPSE-AF with Boston Scientific's RHYTHMIA HDX, Biosense Webster's CARTO 3 and Abbott's Ensite systems, all with contact-force sensing catheters, we are now closer to realizing that promise. Furthermore, the 90-day remapping procedures have provided invaluable data to optimize the parameters of this complex form of energy and should be mandatory to compare efficacy outcomes across trials that vary in ablation technology and patient profiles. There is no doubt now that focal PEF ablation with CENTAURI yields durable lesions without gaseous emboli," 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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Source: Galaxy Medical, Inc.