Maxwell Biomedical Initiates First-in-Human Trial to Assess the Safety and Efficacy of a Novel Pacing Intervention in Patients with Atrial Fibrillation

Spatial Resynchronization™ Therapy (SR™ T) Successfully Terminated Atrial Fibrillation

SAN DIEGO, Calif., July 14, 2022. Maxwell Biomedical announced today that it has initiated its First-in-Human Clinical Trial "Initial Experience with Spatial Resynchronization Therapy in Patients with Atrial Fibrillation (SR-TheAF)" at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia. The study is designed to test the acute safety and efficacy of Spatial Resynchronization™ Therapy (SR™T) in patients with a history of atrial fibrillation (AF). The study will enroll up to 30 patients. During the initial studies, AF was successfully detected and termination with SRT pacing was demonstrated.

Spatial Resynchronization Therapy is Maxwell's proprietary algorithm designed specifically to treat AF. Once AF is detected, SRT delivers pacing stimuli across ~~a~~ spatially distributed array of electrodes placed on the pericardial wall of the left atrium. Pacing stimuli, which are imperceptible to the patient, are precisely delivered to restore normal rhythm.

"We are very excited about the acute performance of SRT in this first series of patients," stated Randy Werneth, CEO of Maxwell Biomedical, "This represents a major milestone in our development pathway to bring a device-based treatment option to patients with AF." Working alongside the surgical team in Tbilisi was Mehdi Razavi, MD, an entrepreneurial electrophysiologist from the Texas Heart Institute in Houston Texas, who has been working closely with the Maxwell Biomedical team to develop and pre-clinically test the SRT concept. "In the past, pacing was tried with limited success to convert AF to a normal rhythm," said Dr. Razavi, "SRT is a new methodology, based on insights gained from past experiences and rooted in the underlying biophysics of human fibrillatory conduction."

AF is the most common heart arrhythmia affecting over 33 million patients worldwide.[1] It occurs when the upper chambers beat uncontrollably and are out of synchronization with the lower chambers of the heart. The lack of coordinated contractions during prolonged episodes of AF increases the likelihood of blood clot formation and reduces the amount of blood available to pump to the body. AF increases stroke risk five times[2], increases mortality rates two-fold in heart failure patients[3] and costs the United States healthcare system $26B annually[1]. Current AF treatment options include outpatient cardioversion, rate or rhythm control medications and catheter ablation. SRT would offer patients a non-destructive, minimally invasive option to treat their AF.

About Maxwell Biomedical

We are a development stage, science driven, innovative medical technology company with outstanding people dedicated to advancing long-term solutions for patients with Atrial Fibrillation.
Maxwell is developing a first of its kind, non-ablative, atrial pacing device that automatically detects AF and imperceptibly delivers Spatial Resynchronization Therapy (SRT) to restore and maintain a normal heart rhythm. Device monitoring and cloud connectivity ensures active and continuous patient care and management. Founded in 2019, Maxwell Biomedical is based in San Diego, CA.

1. Chugh SS et al. *Worldwide epidemiology of atrial fibrillation. A global burden of disease study 2010.* Circulation;129:2014.
2. Virani SS et al. *Heart disease and stroke statistics – 2021 update: a report from the American Heart Association*. Circulation;143:2021.
3. Chamberlain AM et al. *Atrial Fibrillation and Mortality in Heart Failure*. Circ: Heart Failure;4(6):2011.