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A New Age for Atrial Fibrillation Ablation: BioSig's PURE EP Enhanced Electrophysiology Recording System

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MINNEAPOLIS, MN, July 26, 2016 /PRNewswire/ - An arrhythmia is when the heart beats too slowly, too fast, or in an irregular manner. A few conditions falling under this category include ventricular fibrillation (VF), ventricular tachycardia (VT) and atrial fibrillation (AF). AF is far and away the most prevalent of diagnoses, affecting approximately 33 million people worldwide, and 6.1 million in the U.S. according to the Centers for Disease Control and Prevention (CDC).

Dr. Sumeet Chugh, M.D., the associate director of the Cedars-Sinai Heart Institute and author of a World Health Organization study on the condition, describes AF as a "huge public health burden" that is on the rise. He also states, "atrial fibrillation has a huge cost in every sense of the word." The CDC estimates that AF results in about 750,000 hospitalizations annually and costs the country about $6 billion each year.

While AF sufferers can lead long and active lives, there is a well-documented correlation between AF and stroke and other associated risks, such as heart failure. Minimally invasive procedures, such as radiofrequency catheter ablation and Medtronic's new cryoballoon ablation, involve disabling tiny portions of heart tissue in an attempt to correct dysfunctional electrical signals that control the heartbeat. To achieve this, radiofrequency ablation, which has been around for more than twenty years, uses heat and cryoballoon ablation uses extreme cold. These techniques often deliver a meaningful response by reducing the frequency of episodes where the heart's atria spasms, but AF therapy is still not a perfect science. New electrophysiology (EP) device technologies on the horizon could improve success rates.

"Surprisingly, many of the technologies used today in ablation procedures are over a decade old," said Ken Londoner, founder and executive chairman of medical device maker BioSig Technologies, Inc. (OTCQB: BSGM), in a phone conversation. "Some patients have to undergo more than one ablation procedure without clinical success, which is expensive and still leaves them at a higher risk of co-morbidities associated with AF."

According to Londoner, one of the major factors to improving success rates is in the technology that assists the electrophysiologist during the ablation procedure. Today's EP systems have limited dynamic range, which translates into problems in needing to amplify small signals in order to see them, which ultimately distorts resolution and saturates large

signals. Amongst other things, electrical noise is also an issue, making it difficult for clinicians to differentiate real physiologic signals from noise.

BioSig is creating a new market segment with its PURE EP System, a surface electrocardiogram and intracardiac multichannel signal acquisition and analysis system, to overcome these obstacles. The PURE EP System has been developed to provide a high resolution, high fidelity technology that minimizes noise without compromising signal quality. The device is designed to acquire cardiac signals at levels the company believes are undetectable by any EP recording system marketed today, and provide visualization tools so clinicians can make more informed decisions in real-time during the procedure. The aggregate benefits of the proprietary hardware and signal processing are designed to maximize ablation efficiency and minimize need for repeated procedures.

The concept for PURE EP was developed five years ago in collaboration with Texas Cardiac Arrhythmia Institute. Since, BioSig has worked with some of the foremost cardiac arrhythmia centers in the country, including UCLA Health, Mount Sinai Medical Center in New York, UH Case Medical Center in Cleveland and Mayo Clinic in Rochester, Minnesota to develop PURE EP and conduct a series of pre-clinical trials.

Because PURE EP qualifies with the FDA as a Class II medical device, extensive clinical trials are not required. A 510(k) marketing clearance creates a relatively short path to commercialization and only requires BioSig to show the device to be safe and substantially equivalent to another product on the market (predicate device). BioSig intends to file its 510(k) application in the first half of 2017.

If approved for marketing, BioSig is entering into a large (estimated at approximately $4 billion currently) and growing EP market, with what could arguably be considered a better product. In addition to other disruptive qualities, Dr. Samuel Asirvatham, a professor of medicine in the Mayo Clinic's Division of Cardiovascular Diseases within the Department of Internal Medicine, noted in a BioSig presentation that, "[PURE EP's] improved resolution may translate to better ability to pick up specific signals and relate them to specific structure and substrate." He also added, "the display options are also more intuitive and flexible. For example, different filtering can be applied to the same signal and displayed as separate, simultaneous signals. *Presently this is not possible with the existing systems to my knowledge*."

Analysts at Transparency Market Research forecast the global market for EP devices will grow at a 12.1 percent compound annual growth rate, from $2.5 billion in 2012 to $5.5 billion by 2019, making it one of the fastest growing medical device segments. In the United States alone, the number of AF and VT arrhythmia ablations is forecast to grow at 10.5 percent from 2012 to 2017.

The medical device space is extremely active due to the premium that Wall Street places on companies with disruptive technologies. GE Healthcare controls the lion's share of the EP recording device market with its CardioLab EP recording system. Boston Scientific, St. Jude Medical (which Abbott Labs announced acquiring for $25 billion in April), Medtronic and Johnson & Johnson all have significant control of the global EP market. Interestingly, several members of BioSig's management and board of directors have previously held leadership positions within these and similar companies.

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