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BioSig Announces Submission of FDA 510(k) Application for PURE EP(TM) System

SANTA MONICA, Calif., March 28, 2018 (GLOBE NEWSWIRE) -- BioSig Technologies, Inc. (OTCQB:BSGM) announced that the Company has filed 510(k) application to the U.S. Food and Drug Administration (FDA) for its first product, PURE EP(TM) System.

PURE EP System is a surface electrocardiogram and intracardiac multichannel recording system that acquires, processes and displays high fidelity cardiac recordings required during electrophysiology studies and catheter ablation procedures. The non-invasive PURE EP System is categorized as a Class II medical device according to the FDA and is subject to 510(k) performance standards and regulatory controls. The PURE EP System aims to minimize noise and artifacts and acquire high fidelity cardiac signals, which will potentially increase these signals' diagnostic value, and offer improved accuracy and efficiency of the EP studies and related procedures.

Atrial fibrillation is the most common arrhythmia currently affecting 33.5 million people worldwide, with 6.1 million people in the U.S. Atrial fibrillation increases the risk of stroke by 4 to 5 times and contributes to ca. 750,000 hospitalizations per year. The current market of EP is currently estimated at $4.6 billion and growing at 10.5% rate annually.

Between 2015-2018 BioSig has performed eleven pre-clinical studies at Mayo Clinic in Rochester, MN and one study at Mount Sinai Hospital in New York, NY. The results of these studies have been documented in seven peer reviews, including the Journal of Innovations in Cardiac Rhythm Management (JICRM) and the Journal of the American College of Cardiology (JACC).

In October 2017 BioSig announced the results of a nationwide survey of electrophysiologists. Survey respondents rated all six features of the PURE EP System as being 'Very Helpful' for their ablations, emphasizing overall 'noise' reduction and improved signal clarity/accuracy as key benefits.

In November 2017 BioSig engaged California based Sherpa Technology Group as its intellectual property advisors.

"Our Company's mission is to improve the standards of patient care worldwide. Submission of 510(k) application is a major milestone, which, once completed, will allow us to bring the PURE EP System to the EP community. Patient-centred innovation is at the heart of what we do, and we will continue to work rigorously to address unmet clinical needs," commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies, Inc.

About BioSig Technologies
BioSig Technologies is a medical device company developing a proprietary biomedical signal processing technology designed to improve the $4.6 billion electrophysiology (EP) marketplace (www.biosigtech.com). Led by a proven management team and a veteran, independent Board of Directors, Los Angeles-based BioSig Technologies is preparing to commercialize its PURE EP(TM) System. The technology has been developed to address an unmet need in a large and growing market.

The Company's first product, PURE EP System, is a novel cardiac signal acquisition and display system which is engineered to assist electrophysiologists in clinical decision making during procedures to diagnose and treat patients with abnormal heart rates and rhythms. BioSig's main goal is to deliver technology to improve upon catheter ablation treatments for the prevalent and deadly arrhythmias, Atrial Fibrillation and Ventricular Tachycardia.

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