

BioSig Technologies To Commence First-in-Human Studies at Mayo Clinic

Leading Institution to Become the Second Center after TCAI to Launch the Studies with PURE EP System

Santa Monica, CA, Dec. 06, 2018 (GLOBE NEWSWIRE) -- BioSig Technologies, Inc. (NASDAQ: BSGM), a medical device company developing a proprietary biomedical signal processing platform designed to address an unmet technology need for the \$4.6 billion electrophysiology (EP) marketplace, today announced that the Company has signed an agreement with Mayo Clinic to conduct First-in-Human studies using the PURE EP™ System.

These First-in-Human studies are aimed at validating the safety and efficacy of the PURE EP™ System during mapping and ablation procedures in the cardiac EP lab. Mayo Clinic has conducted twelve pre-clinical studies to date using the PURE EP™ System, results of which have been <u>published</u> in a number of journals, including<u>The Journal of Innovations in Cardiac Rhythm Management</u>. Collected data and physician experience arising from this non-randomized First-in-Human study will be documented and presented in the form of publications and lay the foundation for future larger clinical trials.

Mayo Clinic becomes the second center to launch pilot First-in-Human studies ahead of BioSig's targeted commercial launch of its first product, PURE EP™ System in 2019. BioSig announced on November 28, 2018 that it begins installations of the first systems at Texas Cardiac Arrhythmia Institute in Austin, Texas. BioSig signed a 10-year collaboration agreement with Mayo Clinic in March 2017 and announced a new research agreement focusing on development of additional advanced features and potential new applications of the PURE EP™ System on November 13, 2018.

The study will be conducted under leadership of K. L. Venkatachalam, M.D. and Samuel J. Asirvatham, M.D., Medical Director of the Electrophysiology Laboratory.

"We are extremely proud to be working with Dr. Venkatachalam and Dr. Asirvatham on collection of the First-In-Human data. Our continued collaboration with Mayo Clinic remains one of our biggest assets, and we couldn't wish for a better team to launch this new clinical milestone, which is essential to unlocking better treatments for all arrhythmia patients and creating shareholder value for everyone who continues to support our Company," commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies.

The PURE EP™ System aims to minimize noise and artifacts and acquire high-fidelity

cardiac signals. Improving fidelity of acquired cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures. The PURE EP™ System takes advantage of improvements in hardware design as well as signal processing software to produce better quality signals to distinguish scar from healthy tissue, and also use tissue properties to estimate the force being applied to tissue. These advantages could improve safety and efficacy of ablation procedures. Initial pre-clinical studies have shown the benefits of this approach.

Mayo Clinic, Dr. K.L. Venkatachalam and Dr. Samuel Asirvatham have a financial interest in the technology referenced in this news release. Mayo Clinic will use any revenue it receives to support its not-for-profit mission in patient care, education and research.

About BioSig Technologies

BioSig Technologies is a medical technology company developing a proprietary biomedical signal processing platform designed to improve the 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™ 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 potentially deadly arrhythmias, Atrial Fibrillation and Ventricular Tachycardia. BioSig has partnered with Minnetronix on technology development and has received FDA 510(k) clearance for the PURE EP™ System in August 2018.

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forwardlooking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (ii) difficulties in obtaining financing on commercially reasonable terms; (iii) changes in the size and nature of our competition; (iv) loss of one or more key executives or scientists; and (v) difficulties in securing regulatory approval to market our products and product candidates. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements

as a result of new information, future events or otherwise.

Contact:
Natasha Drapeau
BioSig Technologies, Inc.
Executive Vice President
12600 Hill Country Blvd R-275
Austin, TX 78738
ndrapeau@biosigtech.com
512-329-2643



Source: BioSig Technologies, Inc.