November 27, 2018

BioSig Technologies Signs Agreement with Texas Cardiac Arrhythmia Institute for First–in-Human Studies

Santa Monica, CA, Nov. 27, 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 Texas Cardiac Arrhythmia Institute (TCAI) at St. David's Medical Center in Austin, Texas to conduct First-in-Human studies using the PURE EP™ System.

These First-in-Human studies are aimed at validating the key value proposition elements of the PURE EP™ System that have already been established in pre-clinical studies and published to date in a number of journals, includingThe Journal of Innovations in Cardiac Rhythm Management. Collected data and physician experience arising from the First-in-Human studies will be documented and presented in the form of publications, clinical abstracts or late-breaking news.

Commencement of First-in-Human studies is the initial step in the Company's targeted commercial launch of its first product, PURE EP™ System. The PURE EP™ System is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory. 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.

Andrea Natale M.D., F.A.C.C., F.H.R.S., F.E.S.C., Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center will conduct the First-in-Human study.

A world recognized leader in the field of electrophysiology, Dr. Natale is known as a dedicated clinician, academician and researcher. He is an author of over 600 publications related to treatments of arrhythmia. Prior to joining TCAI, Dr. Natale was a member of the Cardiovascular Medicine Department at the Cleveland Clinic from 1999 to 2007, and served as Section Head for the Department of Cardiac Pacing and Electrophysiology and as Medical Director for the Cleveland Clinic's Center for Atrial Fibrillation. In 2006, Dr. Natale was named to the Food and Drug Administration's Task Force on Atrial Fibrillation.

“To better understand complex arrhythmia disease states, the ability to detect the smallest of electrical activity in various clinical situations has been a critical need for our industry. I am looking forward to the possibility that the PURE EP System will uncover these signals and advance treatment options so physicians can make more informed decisions for our patients,” commented Dr. Natale.

“BioSig reached another important milestone after achieving FDA clearance in August 2018 and uplisting to Nasdaq in September 2018. We opened an office in Austin, TX, earlier this year in anticipation of our present needs, and are now focused on providing TCAI full support during the First-in-Human use of our technology, which will preface our commercial launch in the U.S. in May 2019. Dr. Natale inspired the founding of our Company and has chaired our Scientific Advisory Board since 2011. We are proud to be working with Dr. Natale and his team during this important stage of our Company’s growth,” commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies.

About Texas Cardiac Arrhythmia Institute
Located at St. David’s Medical Center in Austin, Texas, the Texas Cardiac Arrhythmia Institute is a uniquely effective training, research and treatment facility dedicated solely to heart rhythm disorders. It is one of its kind in the world of electrophysiology.

St. David’s is a state-of-the-science medical center with a well-qualified medical support staff. Its robotics, magnetics and other advanced technologies complement the expertise of TCAI’s physicians. The Institute brings TCAI’s respected physicians and researchers together with St. David’s superior facilities to address even the most challenging arrhythmias.

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. Forward-looking 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.

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Source: BioSig Technologies, Inc.