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## Clinical Data Acquired by the PURE EP™ System Published in the Journal of Cardiovascular Electrophysiology

## The PURE EP<sup>™</sup> System is validated in multi-center study as superior to conventional sources of intracardiac signals

Westport, CT, Oct. 04, 2021 (GLOBE NEWSWIRE) --BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), a medical technology company developing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced that an article titled, *"Evaluation of a novel cardiac signal processing system for electrophysiology procedures: the PURE EP 2.0 study"* has been published in the Journal of Cardiovascular Electrophysiology and is available electronically with open access as of September 23, 2021, via the <u>Wiley Online Library</u>.

The PURE EP 2.0 study was conducted at three U.S. hospitals: Texas Cardiac Arrhythmia Institute at St. David's Medical Center, Mayo Clinic Jacksonville, and Massachusetts General Hospital.

The manuscript is co-authored by Amin Al-Ahmad, M.D., FHRS, Bradley Knight, M.D., FHRS, Wendy Tzou, M.D., FHRS, Robert Schaller, D.O., FHRS, Omar Yasin, M.D., Deepak Padmanabhan, M.D., Jason Zagrodsky, M.D., FHRS, Mohammed Bassiouny, M.D., J David Burkhardt, M.D., FHRS, Joseph Gallinghouse Jr., M.D., FHRS, Moussa Mansour, M.D., FHRS, Christopher McLeod, MBChB, Ph.D., FHRS and Andrea Natale, M.D., FHRS, the Principal Investigator of the study. The independent, blinded reviewers were Bradley P. Knight, M.D. (Northwestern University), Wendy Tzou, M.D. (University of Colorado), and Robert Schaller, M.D. (University of Pennsylvania).

Intracardiac signal data of clinical interest were collected during 51 cardiac ablation procedures using the PURE EP<sup>™</sup> System, the signal recording system, and the 3D mapping system at the same time stamps. The samples were randomized and subjected to blinded, head-to-head evaluation by three independent electrophysiologists to determine the overall quality and clinical utility of PURE EP<sup>™</sup> signals when compared to conventional sources. Each reviewer responded to the same (235) signal comparisons using a 10-point rating scale.

Results showed 93% consensus across the blinded reviewers with a 75% overall improvement in intracardiac signal quality and confidence in interpreting PURE EP signals

over the signals from conventional sources.

Further analysis of the responses from the blinded reviewers showed an 83% (p-value <0.001) improved confidence when interpreting complex multi-component signals, leading to a better understanding of the catheter position in relation to the ablation target. Additionally, there was a 73% (p-value <0.001) improved visualization of small, fractionated potentials increasing the proper analysis of scar and abnormal conduction tissue characteristics.

"In order for any new medical technology to be widely adopted and accepted, strong, prospective clinical study results are necessary. The results from the PURE EP 2.0 study clearly validate the clinical importance of our technology and position the Company for continued growth and success. We are grateful for the many physician investigators and research staff who participated in this study and look forward to continuing our clinical work to advance the field of electrophysiology and bioelectronic medicine," commented Kenneth L. Londoner, Chairman, and CEO of BioSig Technologies, Inc.

To date, over 60 physicians have completed over 1400 patient cases with the PURE EP<sup>™</sup> System across thirteen clinical sites.

## About BioSig Technologies

BioSig Technologies is a medical technology company commercializing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals (www.biosig.com).

The Company's first product, PURE EP (tm) 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.

## **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) the geographic, social and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, (ii) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (iii) difficulties in obtaining financing on commercially reasonable terms; (iv) changes in the size and nature of our competition; (v) loss of one or more key executives or scientists; and (vi) 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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