May 18, 2020

FDA Clears the Investigational New Drug Application to Enable the Phase II Trial of ViralClear's Merimepodib, Oral Solution to Treat Adult Patients with Advanced COVID-19, to Proceed

Westport, CT, May 18, 2020 (GLOBE NEWSWIRE) --

- **Phase II clinical trial expected to be conducted at multiple centers in the United States, including three Mayo Clinic sites under the leadership of Andrew D. Badley, M.D., Enterprise Chair of COVID-19 Task Force**
- **Randomized, double blind, placebo-controlled clinical trial to be conducted in adults with COVID-19 who are hospitalized and either require supplemental oxygen or are on non-invasive ventilation or high flow oxygen devices**

BioSig Technologies, Inc. (Nasdaq: BSGM) ("BioSig" or the "Company") and its majority owned subsidiary, ViralClear Pharmaceuticals, Inc. (ViralClear), today announced that the U.S. Food and Drug Administration (FDA) has completed its review of ViralClear's Investigational New Drug (IND) application. The FDA informed ViralClear that it may proceed with a proposed phase II study of merimepodib oral solution in adults with COVID-19 who are hospitalized and either require supplemental oxygen or are on non-invasive ventilation or high flow oxygen devices.

This study will be a randomized, double blind, placebo-controlled trial to evaluate the efficacy and safety of merimepodib as an orally administered treatment. The trial will occur in hospitalized patients who have confirmed infection with SARS-CoV-2 and require supplemental oxygen.

"I'm very pleased to be involved in this planned Phase II study of merimepodib for the treatment of patients with COVID-19 disease," said Andrew D. Badley, M.D., Professor and Chair of Department of Molecular Medicine and the Enterprise Chair of COVID-19 Task Force. "We are grateful to the FDA for their prompt response in helping accelerate opportunities to find treatments for the novel coronavirus. We plan to begin enrollment of this trial as soon as practicable given the importance of finding solutions to this pandemic."

"FDA clearance for our proposed phase II trial to proceed is an important step for the development of merimepodib," commented Jerome B. Zeldis, M.D., Ph.D, Executive Chair, co-founder and acting Chief Medical Officer of ViralClear Pharmaceuticals, Inc. "We intend

to conduct Phase II evaluations of our drug both in the hospital and outpatient settings as part of our clinical development plan."

"We thank the Mayo Clinic for collaborating with us to conduct the trials under the leadership of Professor Badley," said Nick Spring, Chief Executive Officer of ViralClear Pharmaceuticals, Inc. "Of the therapies that are currently being evaluated as treatments and can be available in the short term, we believe that a broad-spectrum antiviral that is orally administered and widely available could be very helpful in addressing the COVID-19 pandemic. We further believe it can play a pivotal role in helping manage this type of public health crisis."

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.

About Merimepodib (MMPD)
Merimepodib, a broad-spectrum anti-viral candidate, that demonstrates strong activity against COVID-19 in cell cultures in laboratory testing and additional antiviral studies are underway. Merimepodib was previously in development as a treatment for chronic hepatitis C and psoriasis by Vertex Pharmaceuticals Incorporated (Vertex), with 12 clinical trials conducted (including 315 chronic hepatitis C patients, 24 psoriasis patients, and 98 healthy volunteers) and an extensive preclinical safety package completed.

A manuscript titled, "The IMPDH inhibitor merimepodib provided in combination with the adenosine analogue remdesivir reduces SARS-CoV-2 replication to undetectable levels in vitro", was submitted to an online peer-reviewed life sciences journal. This manuscript is authored by Natalya Bukreyeva, Rachel A. Sattler, Emily K. Mantlo, John T. Manning, Cheng Huang and Slobodan Paessler of the UTMB Galveston National Laboratory and Dr. Jerome Zeldis of ViralClear Pharmaceuticals, Inc. ("ViralClear") as a corresponding author. This article highlights pre-clinical data generated under contract with Galveston National Laboratory at The University of Texas Medical Branch.

About ViralClear
BioSig's subsidiary ViralClear Pharmaceuticals, Inc., is seeking to develop a novel pharmaceutical to treat COVID-19. Merimepodib is intended to be orally administered, and has demonstrated broad-spectrum in vitro antiviral activity, including strong activity against COVID-19 in cell cultures. Merimepodib has been previously studied in 12 clinical trials, including 5 in patients with hepatitis C (1 Phase 1b, 1 Phase 2, 2 Phase 2a, and 1 Phase 2b), 1 in patients with psoriasis (Phase 2), and six in healthy volunteers (Phase I).

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) 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.

Andrew Ballou
BioSig Technologies, Inc.
Vice President, Investor Relations
54 Wilton Road, 2nd floor
Westport, CT 06880
aballou@biosigtech.com
203-409-5444, x133

Source: BioSig Technologies, Inc.