

FINAL



Media Contact:

Kathryn Morris

Bright Point

M: 914-204-6412

kathryn@brightpointny.com

## **SetPoint Medical Reports Positive Results from Two Bioelectronic Medicine Studies at North American Neuromodulation Society Meeting**

– Company Presented Positive Data on RA 24-Month Follow-up Study and Current Crohn’s Disease Study –

Valencia, CA – January 14, 2018 – [SetPoint Medical](#), a clinical-stage biomedical technology company developing an implantable bioelectronic medicine therapy for chronic inflammatory diseases, presented positive data from two clinical studies in rheumatoid arthritis (RA) and Crohn’s disease (CD) at the North American Neuromodulation Society (NANS) annual meeting, held January 11-14, 2018 in Las Vegas.

Both studies use an implanted device to deliver digital doses of electricity, stimulating the vagus nerve with timed electrical pulses, activating the body’s natural [Inflammatory Reflex](#) to produce a systemic anti-inflammatory effect.

- Oral presentation – “First-in-Class Bioelectronic Therapy for Rheumatoid Arthritis: Two Year Follow-Up,” by David Chernoff, MD, Chief Medical Officer of SetPoint Medical
  - Revealed positive long-term follow-up data from its previously reported first-in-human study of vagus nerve stimulation for RA, published in *Proceedings of the National Academy of Sciences* (PNAS) in 2016
  - The company continued to follow study participants 24 months beyond the end of the published primary study.
  - SetPoint will present full 24-month study results at an upcoming meeting.
- Poster – “Electrical Vagus Nerve Stimulation in Biologic-Refractory Crohn’s Disease Patients,” by Yaakov Levine, PhD, Director of Applied Research at SetPoint Medical and David Chernoff, MD, Chief Medical Officer of SetPoint Medical
  - Open-label pilot study is being conducted at five centers in Europe and includes patients with moderately-to-severely active Crohn’s despite treatment with a tumor necrosis factor (TNF) antagonist drug.
  - Data were presented for the first Cohort of six patients that have completed the study. In these patients, VNS induced clinical and endoscopic improvement in a significant proportion of highly refractory CD patients, measured with Crohn’s Disease Activity Index (CDAI), a tool used to quantify the symptoms of patients with the disease. Severe Crohn’s is defined by a CDAI greater than 450, and remission is defined as a CDAI below 150.

## FINAL

- Results reported 4 of 8 patients with CDAI-70 response, 3 of 8 with CDAI remission and 6 of 8 with reduced SES-CD.
- There were 9 serious adverse events occurring in 5 of 8 patients, all of which were Crohn's disease-related except for 1 (device-related postoperative infection), and 1 early termination.
- This poster was an update of data presented previously.
- The trial is ongoing and fully enrolled.

“The data presented at NAHMS and our ongoing human studies support SetPoint’s development of bioelectronic medicines designed to improve the lives of people suffering from chronic inflammatory diseases. Activation of the Inflammatory Reflex via vagal nerve stimulation provides a novel approach to treating inflammatory diseases currently treated with potent and targeted expensive drugs like TNFa inhibitors,” said David Chernoff, MD, Chief Medical Officer of SetPoint Medical. “In addition to the ongoing Crohn’s study, we are pleased to have initiated a pilot trial in the U.S. for patients with drug-refractory rheumatoid arthritis using SetPoint’s proprietary bioelectronics vagal nerve stimulation device. We look forward to reporting pilot data later this year.”

SetPoint is developing a [novel proprietary bioelectronic medicine platform](#) that activates the body’s natural [Inflammatory Reflex](#) in order to activate systemic anti-inflammatory pathways. The emerging field of bioelectronic medicine aims to address unmet patient needs by delivering targeted digital doses to modulate physiological circuits for treatment of diseases historically treated with drugs.

### **About SetPoint Medical**

[SetPoint Medical](#) is a privately held biomedical technology company dedicated to treating patients with debilitating inflammatory diseases using bioelectronic therapy. SetPoint’s approach is intended to offer patients and providers an [alternative](#) treatment for rheumatoid arthritis (RA) and other chronic inflammatory diseases with less risk and cost than drug therapy.

SetPoint is developing a novel bioelectronic medicine platform that stimulates the vagus nerve to activate the body’s natural Inflammatory Reflex, which is intended to produce a potent systemic anti-inflammatory effect. The company has published positive results from a first-in-human proof-of-concept trial in rheumatoid arthritis in Proceedings of the National Academy of Sciences (PNAS) and presented positive results at the American College of Rheumatology meeting. Current [investors](#) in the company include Morgenthaler Ventures, NEA, Topspin Partners, Medtronic, GlaxoSmithKline’s Action Potential Venture Capital Limited and Boston Scientific. For more information, visit [www.setpointmedical.com](http://www.setpointmedical.com).

# # #