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SetPoint Announces First Trial of Bioelectronic Therapy to Treat Crohn's Disease

– Second Study in Humans to Evaluate Bioelectronic Medicine for Autoimmune Disease –

Valencia, CA – December 4, 2014 – [SetPoint Medical](#), a biomedical technology company developing a bioelectronic medicine therapy for inflammatory diseases, announced today the start of clinical testing to assess safety and efficacy in Crohn's Disease, a debilitating disease caused by inflammation in the digestive tract. The trial launched as gastroenterologists gather this week in Orlando, Florida for "Advances in Inflammatory Bowel Diseases," the Crohn's & Colitis Foundation's annual clinical and research conference.

"Despite recent advances in therapy for Crohn's, most patients do not achieve full disease control, and many who are adequately controlled seek alternatives to standard drug treatments," said Dr. Geert D'Haens, Professor of Gastroenterology at The Academic Medical Center (AMC), University of Amsterdam and Coordinating Investigator for the study. "SetPoint's approach has shown encouraging results in patients with rheumatoid arthritis, and we look forward to evaluating its potential in Crohn's patients in this important new study."

The proof-of-concept study is being conducted at five centers in Europe, and will include patients with moderately-to-severely active Crohn's despite treatment with a tumor necrosis factor (TNF) antagonist drug. The trial will use an implanted device to stimulate the vagus nerve, activating the body's natural [Inflammatory Reflex](#) to produce a systemic anti-inflammatory effect.

"We are very encouraged by the positive results of our study in rheumatoid arthritis using this breakthrough approach to treating autoimmune and inflammatory diseases," said [Anthony Arnold](#), chief executive officer of SetPoint Medical. "We are pleased to launch this new study, which we anticipate will provide further evidence that our approach can have benefits for both patients and caregivers and will reduce healthcare costs."

SetPoint is developing a [novel proprietary bioelectronic medicine platform](#) to treat a variety of inflammation-mediated autoimmune diseases. The emerging field of bioelectronic medicine aims to target disorders historically treated with drugs, instead using advanced implantable devices offering significant advantages. Research in this field is being driven forward by support from several recently announced funding initiatives including the DARPA ElectRx, NIH SPARC, and GlaxoSmithKline Bioelectronics Innovation Challenge programs.

"Millions of people worldwide are living and suffering with Crohn's disease, which causes abdominal pain, severe diarrhea, fatigue, weight loss and malnutrition," said Marjorie Merrick, Vice President of Research Special Projects at the Crohn's & Colitis Foundation of America. "Current treatments include medication,

dietary changes and sometimes surgery, but there is no standard treatment that will work for all patients, and the need for new approaches and new treatment options is great and urgent. We applaud all efforts focused on developing new treatments for Crohn's and look forward to seeing the results of this trial."

About SetPoint Medical

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

SetPoint's novel platform consists of an implantable miniature neuromodulation device, wireless charger and iPad prescription pad application. The system uses vagus nerve stimulation to activate the body's natural [Inflammatory Reflex](#), which produces a potent systemic anti-inflammatory effect. The company presented positive results from a first-in-human open-label proof-of-concept trial in rheumatoid arthritis at the American College of Rheumatology annual meeting in November 2012. The results confirmed extensive preclinical studies and showed clinical efficacy comparable to leading immunosuppressive drugs. SetPoint is headquartered in Valencia, Ca., and current investors in the company include Morgenthaler Ventures, Foundation Medical Partners, Topspin Partners, Covidien Ventures, Action Potential Venture Capital Limited, the GlaxoSmithKline (GSK) new strategic venture capital fund for bioelectronic medicines and technologies, and Boston Scientific. For more information, visit www.setpointmedical.com.

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