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FDA Approves Investigational Device Exemption for SetPoint Bioelectronic Therapy Clinical Study in Rheumatoid Arthritis

Valencia, CA – December 11, 2017 – [SetPoint Medical](#), a clinical-stage biomedical technology company developing an implantable bioelectronic medicine therapy for chronic inflammatory diseases, has received Investigational Device Exemption (IDE) approval from the U.S. Food & Drug Administration (FDA) to initiate a pilot trial in the U.S. for patients with drug refractory rheumatoid arthritis (RA). SetPoint’s proprietary bioelectronic device will be surgically placed on the vagus nerve and activated based on a predetermined dosage schedule to evaluate safety and efficacy.

This multi-center study, “A Randomized Controlled Study of the Safety and Efficacy of Neurostimulation Using a Vagus Nerve Stimulation Device in Patients with Rheumatoid Arthritis,” will assess the safety and efficacy of SetPoint’s proprietary bioelectronic device in adult patients with RA who have failed multiple biologic agents. A total of 15 subjects, aged 22 to 75, will be enrolled across seven U.S. investigational centers.

“We are ready to build on the published positive data from our earlier first-in-human proof-of-concept study of bioelectronic therapy in RA, which significantly improved measures of RA disease activity in this difficult-to-treat patient population and also inhibited cytokine production,” said [David Chernoff](#), MD, Chief Medical Officer of SetPoint Medical. “The new trial will evaluate SetPoint’s advanced generation proprietary miniaturized, rechargeable wireless implanted device. This novel device will be used to stimulate the vagus nerve in order to activate the efferent arm of the Inflammatory Reflex known as the Cholinergic Anti-inflammatory Pathway (CAP).”

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.

“Gaining IDE approval for the clinical trial with our propriety device is an important milestone in moving our bioelectronic medicine program towards commercialization,” said [Anthony Arnold](#), Chief Executive Officer

of SetPoint Medical. “This strengthens our resolve to give physicians a new therapeutic alternative designed to be safer and more cost effective for patients with not only RA but other chronic inflammatory diseases.”

Rheumatoid arthritis is a chronic inflammatory disease that affects 1.3 million people in the United States and costs tens of billions of dollars annually to treat.

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.

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