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SetPoint Medical Reports Positive Long-term Results from its Clinical Study of Bioelectronic Medicine to Treat Rheumatoid Arthritis

 Results presented at Annual European Congress of Rheumatology highlight strong therapy adherence and significant reduction in rheumatoid arthritis symptoms after 24-months of therapy –

Valencia, CA – June 19, 2018 – <u>SetPoint Medical</u>, a clinical-stage biomedical technology company developing bioelectronic therapy for chronic inflammatory diseases, announced positive long-term data for its first-in-human study using bioelectronic medicine for rheumatoid arthritis (RA). Building on the positive 3-month results that were published in *Proceedings of the National Academy of Sciences* (PNAS) in 2016, the follow-up through 24 months demonstrated significant, sustained improvement in clinical disease activity scores and disability indices on bioelectronic therapy. The results were presented in a poster session at the Annual European Congress of Rheumatology (EULAR), held June 13-16 in Amsterdam.

"Reducing disease activity to as low a level as possible is an important goal in the management of patients with RA in order to reduce permanent joint damage and improve quality of life," said David Chernoff, MD, Chief Medical Officer of SetPoint Medical. "Unfortunately, loss of response or intolerance to powerful immunosuppressive targeted biologic agents and problems with adherence with treatment is not uncommon so there is an unmet medical need for alternative approaches for the treatment of RA. These new data document that the initial reduction in RA disease activity observed in the original study can be maintained and continue to improve for up to 24 months of follow-up"

Rheumatoid arthritis is a chronic inflammatory disease that affects 1.5 million people in the United States and costs tens of billions of dollars annually to treat. SetPoint is developing a novel bioelectronic medicine platform that stimulates the inflammatory reflex with digital doses of electricity to produce a systemic anti-inflammatory effect.

In this European study, 17 subjects with moderate to severe RA symptoms were implanted with a vagus nerve stimulating device. Early results demonstrated that bioelectronic therapy significantly reduced rheumatoid arthritis symptoms and inhibited cytokine production at three months. Following completion of

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primary study timepoint, participants had the option of continuing in the follow-up study, and all chose to continue their treatment.

All 17 subjects remained on therapy for 24 months. At the 24-month time point, 87% of the subjects reported had clinically meaningful responses by standard EULAR criteria, demonstrating that bioelectronic medicine has the potential to substantially reduce both clinical RA disease activity and patient disability for two years, with no unexpected safety issues. These improvements were maintained in patients with and without concurrent use of biologic agents.

"Long-term clinical efficacy is important in the development of cost-effective therapy, and we are pleased to report long-term durability of bioelectronic medicine in RA, with safe and efficacious results that have been maintained for two years," said Anthony Arnold, Chief Executive Officer of SetPoint Medical.

SetPoint recently initiated a pilot trial evaluating the company's proprietary device for treatment of drugrefractory RA patients in the U.S.

About SetPoint Medical

<u>SetPoint Medical</u> is a privately held biomedical technology company dedicated to treating patients with debilitating autoimmune inflammatory diseases using bioelectronic medicine. SetPoint's approach is intended to offer patients and providers a treatment <u>alternative</u> for rheumatoid arthritis, Crohn's disease and other chronic inflammatory diseases with less risk and cost than drug therapy. 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.

SetPoint is developing a novel <u>bioelectronic medicine platform</u> that stimulates the vagus nerve with digital doses of electricity designed to activate the cholinergic anti-inflammatory reflex to produce a systemic immunorestorative 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). SetPoint is conducting U.S. clinical trials to advance its bioelectronic technology for chronic inflammatory conditions. Current <u>investors</u> in the company include Morgenthaler Ventures, New Enterprise Associates (NEA), Topspin Partners, Medtronic, GlaxoSmithKline's Action Potential Venture Capital Limited and Boston Scientific. For more information, visit <u>www.setpointmedical.com</u>.

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