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**SetPoint Medical Announces Data Supporting Continued Clinical Development of its Bioelectronic Device for Treatment of Rheumatoid Arthritis (RA)**

*Successful proof-of-concept study demonstrates positive long-term 24-month safety and efficacy data*

*Results to be Presented in Two Poster Presentations Today during the American College of Rheumatology (ACR) / Association of Rheumatology Health Professionals (ARHP) Annual Meeting*

### **Valencia, CA – October 23, 2018** **–** SetPoint Medical, a clinical-stage bioelectronic medicine company developing therapy for chronic autoimmune diseases, today announced long-term, 24-month follow up data from its proof-of-concept study that support the continued clinical development of its proprietary bioelectronic device to treat patients with rheumatoid arthritis (RA). Results will be presented today in two poster presentations during the American College of Rheumatology (ACR) / Association of Rheumatology Health Professionals (ARHP) 2018 Annual Meeting, taking place October 19-23 in Chicago, IL.

Results for the completed proof-of-concept study in Europe supported the initiation of a U.S. Food and Drug Administration (FDA) pilot Investigational Device Exemption (IDE) study evaluating SetPoint’s proprietary miniaturized microregulator, for which the company recently announced completion of enrollment.

Murthy Simhambhatla, President and Chief Executive Officer of SetPoint Medical, said, “It’s exciting to see the development of our unique bioelectronic medicine solution progressing as a fundamentally different treatment option for rheumatoid arthritis. Current autoimmune disease treatments slow disease progression but have significant negative side effects, leave many patients with significantly diminished quality of life, have substantial compliance challenges and are extremely costly. Our alternative approach has the potential to improve upon each of these limitations and we look forward to having our recent clinical advancements presented by leading experts at this year’s ACR/ARHP Annual Meeting.”

**A First-in-Man Bioelectronic Therapy for Biologic-Refractory Rheumatoid Arthritis**

Session Title: Rheumatoid Arthritis – Diagnosis, Manifestations, and Outcomes Poster III: Complications of Therapy, Outcomes, and Measures

Location: Poster Session C, Poster #72161

Date: Tuesday, October 23; 9:00-11:00 a.m. CDT

The poster outlines the results from the initial proof-of-concept, first-in-human European study using a vagus nerve stimulation (VNS) device and the trial design for the U.S. pilot IDE study evaluating safety and tolerability of SetPoint’s proprietary bioelectronic medical device in treating refractory RA patients. The proof-of-concept study evaluating 17 patients showed VNS treatment resulted in significant and clinically meaningful improvement in disease signs, symptoms, and biomarkers; [the 3-month results were published in the Proceedings of the National Academy of Sciences (PNAS)](https://setpointmedical.com/breakthrough-first-in-human-study-shows-vagus-nerve-stimulation-significantly-reduces-rheumatoid-arthritis-symptoms-inhibits-cytokine-production/). Given these results, SetPoint developed its proprietary miniaturized integrated device, which is implanted on the vagus nerve to deliver digital doses to activate the innate inflammatory reflex to produce a systemic anti-inflammatory effect and help regulate the immune system. The U.S. pilot study has completed enrollment of 14 subjects who had failed or were intolerant to multiple, mechanistically different, biologic therapies. Endpoints of the U.S. study include standard RA clinical disease measures as well as quantitative MRI joint scoring, validated RA-specific biomarker panels, autonomic balance measurements, and immune cell bioassays. Bioelectronic medicine has the potential to offer rheumatologists a novel alternative means to treat RA, including those patients who have failed conventional treatments.

**Vagus Nerve Stimulation in Patients with Rheumatoid Arthritis: 24 Month Safety and Efficacy**

Session Title: Rheumatoid Arthritis – Treatments Poster III: Biosimilars and New Compounds

Location: Poster Session C, Poster #73405

Date: Tuesday, October 23; 9:00-11:00 a.m. CDT

The poster reports 24-month follow-up long-term safety and efficacy results from the proof-of-concept EU study evaluating a VNS device to treat RA, as outlined in Poster #72161. All 17 enrolled subjects elected to continue VNS for the duration of the 24-month follow-up and showed significant reduction in RA symptoms and strong therapy adherence. At 24 months, 87% of the subjects reported 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. These long-term data, [initially presented in June 2018](https://setpointmedical.com/setpoint-medical-reports-positive-long-term-results-from-its-clinical-study-of-bioelectronic-medicine-to-treat-rheumatoid-arthritis/), further support SetPoint’s ongoing U.S. prospective double-blinded and controlled pilot IDE study in RA patients.

**About SetPoint Medical**

SetPoint Medical is a privately held clinical-stage bioelectronic medicine company dedicated to treating patients with chronic autoimmune diseases. SetPoint Medical’s bioelectronic medicine platform is intended to offer patients and providers a treatment alternative for rheumatoid arthritis, Crohn’s disease and other chronic autoimmune conditions with potentially less risk and cost than drug therapy. The company is developing a novel bioelectronic medicine platform that stimulates the vagus nerve to activate the inflammatory reflex to produce a systemic immune-restorative effect. Current investors in the company include New Enterprise Associates (NEA), Morgenthaler Ventures, Topspin Partners, SightLine Partners, GlaxoSmithKline’s Action Potential Venture Capital and Boston Scientific as well as an additional undisclosed strategic investor (leading medical device company). For more information, visit [www.setpointmedical.com](http://www.setpointmedical.com).

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