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SetPoint Medical Presents Positive Data from its Clinical Study of Bioelectronic Medicine for Treatment of Crohn's Disease

– Proof-of-Concept Data Presented at Digestive Disease Week in Washington D.C. –

Valencia, CA – June 11, 2018 – [SetPoint Medical](#), a clinical-stage biomedical technology company developing bioelectronic therapy for chronic inflammatory diseases, announced the presentation of positive clinical results from the company's proof-of-concept study using bioelectronic medicine to treat Crohn's disease, a debilitating condition caused by inflammation of the gastrointestinal tract. The data, presented in a poster session at the Digestive Disease Week meeting in Washington, D.C., showed that over 60% of patients achieved significant reductions in their disease activity as assessed by the Crohn's Disease Activity Index (CDAI).

This open-label study was conducted at five European centers and included 16 patients with moderate to severe Crohn's disease with inadequate responses to tumor necrosis factor (TNF) antagonist drugs and other non-TNF targeted biologic agents. All patients were implanted with a vagus nerve stimulating device to deliver digital doses of electricity designed to activate the cholinergic anti-inflammatory reflex to produce a systemic immunorestorative effect.

Improvement was assessed at 16 weeks by measuring the change from baseline in the CDAI, a clinical trial measurement used to quantify disease activity. Severe Crohn's is defined by a CDAI greater than 450. Reduction of 70 or more points on the CDAI scale is considered to be clinically meaningful, and remission is defined as a score below 150.

The interim results show clinical and endoscopic improvement in a significant proportion of highly refractory Crohn's Disease patients:

- Enhanced clinical response, with CDAI scores improvement of 100 or more points, was observed in eight of 16 patients.
- CDAI remission (CDAI below 150) was achieved in four of 16 patients.
- Measures of Simple Endoscopic Score for Crohn's Disease (SES-CD), which evaluates mucosal lesions, showed >25% reductions in six of 15 who underwent the evaluation.
- Fecal calprotectin levels, a biomarker of intestinal inflammation, were reduced in 15 of 16 patients.
- 14 serious adverse events were reported in nine patients, all of which were Crohn's disease-related except for one device-related postoperative infection.

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“These positive clinical trial results, especially in patients who have failed biologic therapy, are very encouraging for patients who are in desperate need of new treatment options for Crohn’s and other inflammatory diseases,” said David Chernoff, MD, Chief Medical Officer of SetPoint Medical. “We saw improvements in the clinical scores and in biomarkers of disease activity within two weeks of therapeutic dosing and a significant clinical response at the 16-week endpoint. Based on these preliminary results, we will continue to evaluate our bioelectronic medicine approach for the treatment of Crohn’s Disease as we are also conducting an ongoing clinical study in rheumatoid arthritis.”

About SetPoint Medical

[SetPoint Medical](#) 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 [alternative](#) 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 [bioelectronic medicine platform](#) 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 [investors](#) 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 www.setpointmedical.com.

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