SetPoint Medical Reports Positive Results from its U.S. Pilot Study in Rheumatoid Arthritis

Results Presented as a Late-breaking Oral Presentation and Included in Official European Congress of Rheumatology (EULAR) 2019 Press Programme and Press Conference

Valencia, CA – June 17, 2019 – SetPoint Medical, a clinical-stage company developing therapy for chronic autoimmune diseases, today announced positive results from its U.S. pilot Investigational Device Exemption (IDE) study evaluating its proprietary bioelectronic medicine device in rheumatoid arthritis (RA). The results were reported as a late-breaking oral presentation, included in the official press programme and presented in an official press conference at the European Congress of Rheumatology (EULAR) 2019.

The U.S. pilot study is a multi-center, double-blind, randomized trial evaluating the safety and tolerability of SetPoint's proprietary, miniaturized microregulator device for the treatment of drug refractory RA. All of the 14 patients enrolled had active RA and prior insufficient response to two or more biologic or targeted synthetic disease modifying anti-rheumatic drugs (DMARDs) having at least two different modes of action. Nine out of the 14 patients had failed to respond to the latest class of targeted synthetic DMARDs, Janus kinase (JAK) inhibitors, after failing to respond to biologic DMARDs. The patients were enrolled in two phases: the first three patients in the open-label phase were implanted and stimulated for one minute, once per day (QD) and, following safety review board approval, the remaining 11 patients were implanted with the device and randomized to one minute of sham, once per day (QD) or four times per day (QID) stimulations through the primary endpoint at 12 weeks.

The data demonstrate that SetPoint's proprietary bioelectronic medicine was well tolerated with no device-related adverse events through 12 weeks. Two notable surgery-related events, that have been reported with other vagus nerve stimulator implantation procedures, were observed and resolved without clinically significant sequelae.

At 12 weeks, positive clinical response was observed in patients who received active stimulation with SetPoint's miniaturized microregulator device. Five out of 10 active stimulation patients, who had failed multiple biologic and targeted synthetic therapies, had clinically meaningful improvement in their signs and symptoms of RA as measured by validated disease measurement instruments such as Disease Activity Score (DAS28-CRP) and Clinical Disease Activity Index (CDAI). Two of these patients achieved DAS28-CRP remission. There was no clinical improvement observed in the four patients assigned to sham stimulation. Treatment with SetPoint's device also demonstrated a greater than 30% decrease, compared to baseline, in bioassay levels of key biomarkers associated with inflammation: IL-1β, IL-6, and TNF-α. Improvements in bone erosion scores of wrist joints, as measured by MRI, correlated with improvement in disease activity; although, there were no changes in joint inflammation scores such as synovitis and osteitis.

"RA is a debilitating condition in which the immune system attacks its own tissue, including joints, and often results in pain, diminished function, bone erosion and joint deformity," said Mark C. Genovese MD, Director of the Rheumatology Clinic in the Division of Immunology and Rheumatology at the Stanford University

School of Medicine and Principal Investigator of the U.S. pilot study. “These results suggest that the SetPoint microregulator device is well tolerated and reduces signs and symptoms of RA in patients who have repeatedly failed treatment with biologics. We are encouraged to continue the evaluation of this therapeutic approach in a larger blinded study in patients with RA.”

SetPoint has translated 20 years of scientific research into clinical practice to activate an innate pathway, the inflammatory reflex, to restore balance to the immune system via its miniaturized microregulator implant.

“These positive results from our U.S. study mark another step closer to providing a new, potentially efficacious, yet less immunosuppressive treatment option for patients who suffer from RA,” said Murthy Simhambhatla PhD, President and Chief Executive Officer of SetPoint Medical. “More than 1.5 million Americans are diagnosed with RA. This development provides a tremendous opportunity to advance a novel alternative for these patients. Based on these results, we look forward to initiating a larger U.S. study of our device, with plans to follow the Pre-Market Approval (PMA) pathway to FDA approval.”

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, inflammatory bowel 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.

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