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SetPoint Medical Completes Enrollment in U.S. Pilot Study Evaluating Bioelectronic Device for Treatment of Rheumatoid Arthritis

Proprietary Device Delivers Doses of Electricity to Activate Systemic Anti-inflammatory Response

Data Readout Expected in Q1 2019

Valencia, CA – October 16, 2018 – SetPoint Medical, a clinical-stage bioelectronic medicine company developing therapy for chronic autoimmune diseases, today announced the completion of enrollment in the U.S. Food and Drug Administration (FDA) pilot Investigational Device Exemption (IDE) study evaluating its proprietary bioelectronic device to treat patients with drug refractory rheumatoid arthritis (RA).

The primary purpose of this multi-center, randomized study is to evaluate safety and tolerability of SetPoint’s proprietary device, which is surgically placed on the vagus nerve. The study includes 14 subjects who had failed or were intolerant to multiple, mechanistically different, biologic therapies. Initial feedback from neurosurgeons performing the implantation has been positive. The company anticipates data readout in the first quarter of 2019.

“While vagus nerve stimulation has demonstrated success in treating neurological conditions such as epilepsy for more than 20 years, this unique therapeutic approach is a compelling and exciting development for the treatment of chronic autoimmune diseases including rheumatoid arthritis,” said R. Mark Richardson, MD, PhD, Associate Professor of Neurological Surgery at University of Pittsburg Medical Center and a surgical investigator in the study. “Implanting this miniaturized, integrated device directly on the vagus nerve was relatively straightforward, requiring only one small incision, and I look forward to the safety and tolerability results.”

SetPoint’s proprietary implant is approximately one inch long. Once surgically placed on the vagus nerve, the device is programmed to automatically deliver electrical doses on a preset schedule.

“Current therapies for rheumatoid arthritis are ineffective in a number of patients, have serious side effects and are costly, so new treatment options are desperately needed for patients who do not respond adequately to drugs approved for treatment of RA,” said David Sikes, MD, a rheumatologist at Florida Medical Clinic in Zephyrhills, Fla. and an investigator in the study. “The development of bioelectronic medicine could offer a completely novel treatment approach for managing our RA patients.”

“Physicians and their patients who have failed conventional therapy desperately need alternative approaches for the treatment of drug refractory RA,” said David Chernoff, MD, Chief Medical Officer of SetPoint Medical. “We were highly gratified with the rapid enrollment in our study and look forward to presenting the results of the trial early next year.”

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.

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