Press Release

Vienna, Austria, August 4, 2025

Syntropic Medical receives IRB approval for new home-based light therapy clinical trial

- On July 15, 2025, Syntropic Medical received approval to initiate a Phase IIa at-home feasibility pilot study in collaboration with the Neuromodulation Lab in the Department of Neurology at NYU Langone Health, Grossman School of Medicine, New York, United States.

- The NEON clinical trial investigates home-based 60 Hz intermittent light stimulation (ILS) for adults with moderate to severe major depressive disorder (MDD).

- This study follows the LUX clinical trial, an early feasibility First-in-Patient study currently ongoing in clinic in a small cohort of moderate MDD patients at the Institute of Psychiatry, University Hospital of São Paulo, Brazil.

- HAVEN, Syntropic's novel medical device, delivers non-invasive, 60 Hz intermittent light stimulation (ILS) to promote juvenile neuroplasticity and relieve symptoms of depression.

On July 15, 2025, Syntropic Medical reached a new milestone with IRB approval for its second clinical trial on 60 Hz light therapy. This study will evaluate home-based treatment over three weeks of stimulation, followed by two weeks of observation. It marks the company's first formal step into decentralized care model for depression.

"*Remote care opens the possibility of reaching patients where they are. This study tests whether we can offer our therapy in a safe and scalable way beyond the clinic,"* said Mark Caffrey, CEO at Syntropic Medical. *"Our goal is not only innovation in treatment mechanism, but also in accessibility."*

Major depressive disorder remains a leading cause of disability worldwide, affecting over 20 million adults in the U.S. in 2019. Conventional treatments like antidepressants often fail to achieve full remission and bring difficult side effects. Nearly 70% of patients do not respond adequately, prompting the need for alternative approaches.

Syntropic Medical is addressing this gap with a non-invasive therapy based on 60 Hz **intermittent light stimulation (ILS)**. This technique, shown in previous studies with healthy individuals and depression patients to be safe and to promote juvenile neuroplasticity, targets the brain's ability to adapt and rewire: a key element in depression recovery.

The Clinical Trial

The upcoming clinical trial is designed to evaluate the feasibility, safety and tolerability of intermittent light stimulation (ILS) in adults with moderate to severe depression. It involves 40 participants, aged between 18 and 59, each diagnosed with a major depressive episode (DSM-5) and maintaining a stable antidepressant regimen for at least six weeks. Over the course of three weeks, each participant undergoes 15 stimulation sessions at home. These sessions are followed by clinical follow-up visits, and efficacy is measured through changes in HDRS-17 scores and other validated scales assessing depression and anxiety symptoms.
The clinical trial is fully home-based, conducted in collaboration with the Neuromodulation Lab in the Department of Neurology at **NYU Langone Health,** ranked #1 in the U.S. for neurology and neurosurgery by U.S. News & World Report.
The Neuromodulation Lab is led by **Prof. Leigh Elkins Charvet, PhD**, Professor of Neurology and Director of the transcranial Direct Current Stimulation (tDCS) Program at NYU Grossman School of Medicine.
The principal investigator of the NEON clinical trial is **Dr. Giuseppina Pilloni, PhD**, Research Assistant Professor in the Department of Neurology at NYU Grossman School of Medicine and co-leader of the Neuromodulation Lab at NYU Langone.

About Syntropic

Syntropic is an Austria-based clinical stage medical device company spun out of the Institute of Science and Technology Austria (ISTA) by Mark Caffrey, Jack O'Keeffe, Dr. Alessandro Venturino, and Prof. Sandra Siegert. The company is developing new technologies that enhance the brain's neuroplasticity, allowing for the treatment of psychiatric disorders and the improvement of cognition. Syntropic's mission is to advance mental health care through the development of innovative technologies that target underlying causes of neuropsychiatric disorders such as depression.

About Researchers Prof. Leigh E. Charvet and Dr. Giuseppina Pilloni

Prof. Leigh E. Charvet, PhD

Professor in the Department of Neurology, Director of NYU Langone's tDCS program and Director of Multiple Sclerosis Comprehensive Care Center Research. She is a licensed clinical neuropsychologist with more than 30 years of clinical research experience.

Prof. Charvet is a world-renowned expert in the field of non-invasive brain stimulation and telehealth. Her career is focused on advancing the understanding and treatment of neurological diseases, particularly motor and cognitive impairments, including conditions such as depression. She has worked to develop telehealth options for interventions that can lead to improved quality of life.
She has led a large research program on the use of non-invasive brain stimulation focused on the at-home use of tDCS to evaluate its clinical benefit and to provide tDCS tele-treatment as innovative care.

Dr. Giuseppina Pilloni, PhD

Research Assistant Professor in the Department of Neurology at NYU Grossman School of Medicine.
She joined the Charvet Neuromodulation Lab to research the mechanisms of action of non-invasive brain stimulation.

Dr. Pilloni's work focuses on optimisation of tDCS, and on developing wearable, digital biomarker tools for at-home use in neurological conditions. She helped scale remotely supervised at-home tDCS, overseeing over 6,700 home-based sessions. She integrates physiological signal and wearable sensor analysis to monitor and manage symptoms at a distance.

About NYU Langone Health, Grossman School of Medicine

The Department of Neurology at NYU Langone Health is a premier center for neurological research, education and clinical care across the United States, **ranked No. 1** in Neurology by *U.S. News & World Report* for the fourth consecutive year in 2025. Its tDCS Program provides home-based transcranial direct current stimulation, recognised internationally for advancing non-invasive brain stimulation in mood, fatigue, cognitive and motor recovery. In 2021 the department also launched the first at-home tDCS telehealth programme under Dr. Leigh E. Charvet to extend access for depression and other neurologic conditions. With robust clinical trials, remote-supervised protocols, state-of-the-art tele-neuromodulation infrastructure and multidisciplinary collaboration among neurology, neuropsychology and rehabilitation teams, the department stands at the forefront of neuromodulation innovation in mental health.

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