Press Release

Vienna, Austria, September 5, 2025

Syntropic initiates first patient stimulation in home-based depression clinical trial

- On September 5, 2025, Syntropic Medical achieved a significant milestone with the first at-home patient stimulation (First Patient First Visit) in its Phase IIa clinical trial on depression.
- The NEON trial explores home-delivered 60 Hz intermittent light stimulation (ILS) in adults diagnosed with moderate to severe major depressive disorder (MDD). It is conducted in collaboration with the Neuromodulation Lab at the Department of Neurology, NYU Langone Health, Grossman School of Medicine, New York, United States.
- This study builds upon the LUX trial, an ongoing first-in-patient feasibility study in-clinic with a smaller group of 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 alleviate depressive symptoms.

On September 5, 2025, the company reached a key clinical milestone with the First Patient First Visit (FPFV) in its light-based therapy trial. The study is testing a three-week course of home treatment followed by a two-week observation period. This represents Syntropic's first formal move toward a decentralized care model for depression.

"By bringing treatment into the home, we remove barriers to access and reduce costs. This approach is especially valuable for patients in rural areas who often face long travel to reach care," said Jack O'Keeffe, CTO of Syntropic Medical.

Major depressive disorder (MDD) remains one of the leading causes of disability worldwide. In 2019, more than 20 million adults in the U.S. were affected. Traditional treatments such as antidepressants often leave patients with incomplete remission and difficult side effects. Around 70% of individuals fail to respond adequately, highlighting the urgent demand for new solutions.

Syntropic Medical is addressing this need with its non-invasive, 60 Hz **intermittent light stimulation** (ILS)-based therapy. Previous studies in both healthy individuals and patients with depression have demonstrated the safety and potential of ILS to enhance neuroplasticity, a critical mechanism for recovery in depression.

The Clinical Trial

The upcoming clinical trial is designed to evaluate the feasibility, safety and tolerability of intermittent light stimulation in adults with moderate to severe depression. It involves 40 participants, 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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IMAGE 1:

Home-based treatment