



NeuroRx Announces First Human Trial Results Targeting Sustained Treatment of Bipolar Depression & Suicidality

Journal of Clinical Psychiatry publishes initial report of human study which showed 50% reduction in symptoms of depression and 75% reduction in suicidality

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[NeuroRx, Inc.](#), a clinical phase pharmaceutical company, reports first-in-man efficacy data for a newly-purposed class of drugs targeted towards rapidly reducing symptoms of depression and suicidality in patients with bipolar disorder and maintaining that effect over time. The peer-reviewed open label study in 8 patients, elements of which were published today in the *Journal of Clinical Psychiatry*, demonstrated a 50% reduction in symptoms of depression and a 75% reduction in suicidality in patients with treatment-resistant bipolar depression. While the use of ketamine for rapid reversal of depression is known, though not yet approved by FDA, its effect is known to be short-lived. This is the first clinical report showing that the ketamine effect can potentially be sustained for two months with additional agents. Elements of this study were presented earlier at the American College of Neuropsychopharmacology.

"Despite extensive evidence that 25% to 50% of those with bipolar depression attempt suicide and far too many succeed, there is currently no FDA-approved treatment for active suicidality in bipolar depression," said Jonathan Javitt, M.D., M.P.H., CEO. Javitt has previously been instrumental in developing high-impact drugs for Merck, Pfizer, Pharmacia, and Allergan and was appointed by Presidents Clinton and Bush to serve as a White House healthcare advisor.

"An FDA-approved treatment for bipolar depression with suicidality would address a critical unmet medical need and would bring hope to both patients and their loved ones around the world," said Wayne Pines, a former Associate Commissioner of the US Food and Drug Administration (FDA).

The study was authored by Drs Kantrowitz, Halberstam, and Gangwisch, who were neither funded by nor associated with NeuroRx. As stated by the authors, "These findings provide proof-of-concept for further study of combined treatment with NMDAR antagonists and FDA-approved medications for bipolar depression."

Unlike most conventional antidepressant drugs which target the brain's serotonin pathway, ketamine and D-cycloserine target the brain NMDA receptor, a receptor first characterized by the inventor Prof. Daniel Javitt, M.D., Ph.D., in conjunction with psychiatric illness in 1991 and characterized over 25 years of academic research.

NeuroRx, Inc. is pioneering a staged treatment approach in which ketamine administration is followed by a combination of D-cycloserine and an FDA-approved mood stabilizer in order to maintain the ketamine effect. The combination is trademarked Cyclurad™ by the Company and was described in a patent application filed in 2013. This is the second peer-reviewed human study in which D-cycloserine has shown a statistically-significant antidepressant effect, but the first to use this compound to as a follow-on to ketamine.

"These first-in-man data are very encouraging. If these findings can be confirmed in a larger scale study, Cyclurad could, if approved by FDA, potentially achieve important benefits for people with bipolar depression and suicidality," said Chaim Hurvitz, a founding investor and Director of NeuroRx.

The study was registered on ClinTrials.gov. The results describe an investigational therapy that is not currently marketed for human use. The individual elements of the treatment consist of drugs approved by FDA for other indications and that are being investigated for use in bipolar depression and suicidality. The next step is a larger scale clinical trial.

About bipolar depression

More than 3 million Americans have bipolar depression, sometimes known as manic depression,[1] a subset of whom have active suicidality. Those with bipolar depression are more than twice as likely to commit suicide compared with patients who have other forms of depression.[2] Between 25% and 50% will attempt suicide at some point in their lives. Overall, patients with treatment resistant depression from all causes cost the healthcare system more than \$120 billion annually.

About NeuroRx, Inc.

NeuroRx, Inc., is a privately-funded, clinical stage pharmaceutical company that is developing Cyclurad™, a proprietary formulation of D-cycloserine and Lurasidone, intended for the treatment of bipolar depression and suicidality. The Company is conducting R&D activities in the United States and Israel. More information at <http://www.neurorxpharma.com>

1. Holma, K, Haukka J, Suiminen K, Differences in incidence of suicide attempts: Bipolar Disorders 2014; 16: 652-661

2. "Suicide, Facts at a glance," US CDC, National Center for Injury Prevention and Control

Media Kit: <http://bit.ly/1J2caOS>

Media contact:

Leron Kornreich

Silicon Valley Communications

Leron@siliconVPR.com

+1-415-937-1724

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