May 30, 2019

NeuroRx Reports Phase 2 Efficacy for NRX-101, a Breakthrough Therapy Targeting Suicidal Bipolar Depression

Findings suggest potential efficacy for NRX-101 in maintaining remission from Severe Bipolar Depression with Acute Suicidal Ideation following initial stabilization with ketamine.

PHILADELPHIA, May 30, 2019 /PRNewswire/ -- NeuroRx, a clinical stage biopharma company focused on development of drugs to target suicidal depression and PTSD, announced statistically significant final results from its Phase 2 STABIL-B study of NRX-101 versus lurasidone in patients with Severe Bipolar Depression and Acute Suicidal Ideation or Behavior (ASIB). The multicenter study included investigators from Harvard/Mass General, University of Alabama Birmingham, and the Baylor College of Medicine.

Based on the results of this study NRX-101 was granted Breakthrough Therapy Designation by the US FDA. Findings will be presented by the Company's CEO at the upcoming BIO International Meeting in Philadelphia on June 3, 2019 at 2:30pm.

In this double-blind study, patients with Severe Bipolar Depression and ASIB, received either NRX-101 or lurasidone after stabilization with a single intravenous infusion of NRX-100 (ketamine). The objective was to test a non-addictive, non-hallucinogenic, safe, home-use oral drug as an alternative to repeated use of ketamine in patients with Severe Depression and Acute Suicidal Ideation or Behavior.

Patients who received NRX-101 following a single dose of ketamine demonstrated significantly lower ($P<.02$) levels of depression as measured on the BISS-derived Montgomery Asberg Depression Rating Scale (MADRS) compared to those in the control group who received lurasidone alone. None of the 12 NRX-101-treated patients met the trial's definition for relapse, while 2 of the 5 lurasidone patients suffered relapse. Relapse was defined as a ≥50% increase in MADRS depression scores versus baseline, suicidality levels requiring hospitalization (C-SSRS ≥4)[1], the need for a new treatment plan.

Overall the drug was well tolerated, with no serious adverse events or discontinuations for side effects. Hallucinations and dissociative side effects, along with blood pressure increases were seen during ketamine infusions, as expected. However, these effects were not seen in association with oral NRX-101.

NRX-101 is a patented, oral, fixed-dose combination of D-cycloserine (DCS), an NMDA antagonist, and lurasidone, which has 5-HT2a receptor antagonist activity. NMDA antagonists are a newly-developed class of antidepressant drugs, whereas most currently approved antidepressant drugs with the exception of intranasal Esketamine®, operate on the brain's Serotonin or Norepinephrine axis. Unlike ketamine, NRX-101 is not addictive, does not cause hallucinations, has no known potential for neurotoxicity, and can be given by mouth.

"To our knowledge, this is the first well-controlled study in which patients with Severe Bipolar Depression and Acute Suicidal Ideation have been maintained in remission with an oral drug regimen," said Dr. Fred Grossman NeuroRx's Chief Medical Officer. "This is a population of patients who frequently require prolonged hospitalization and electroshock therapy and who have a 20% chance of dying from suicide at some point."

"For too long, patients with bipolar depression and especially those with suicidal ideation have been excluded by the pharmaceutical industry from clinical studies of oral antidepressants. NeuroRx aims to bring hope to a

population of patients with a lethal brain condition, who have extraordinary potential to lead productive, and successful lives," said Dr. Jonathan Javitt, co-founder, CEO, and Chairman of NeuroRx.

NeuroRx has now initiated its pivotal P2b/3 study of NRX-101 under Special Protocol Agreement (SPA) with the FDA.

Learn more at NeuroRxpharma.com

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[1] Columbia Suicide Severity Rating Scale; https://cssrs.columbia.edu/wp-content/uploads/ScoringandDataAnalysisGuide-for-Clinical-Trials-1.pdf

View original content:http://www.prnewswire.com/news-releases/neurorx-reports-phase-2-efficacy-for-nrx-101-a-breakthrough-therapy-targeting-suicidal-bipolar-depression-300858814.html

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Released May 30, 2019

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