



## **NeuroRx Signs Agreement With U.S. Dept. of Veterans Affairs and Baylor College of Medicine for Clinical Trial of First Drug Regimen Targeting Severe Bipolar Depression in Patients With Acute Suicidal Ideation & Behavior (ASIB)**

**Third clinical research site for NRX-100 / NRX-101 phase 2B/3 clinical study**

WILMINGTON, Del., Dec. 27, 2017 / [PRNewswire](#) / -- NeuroRx, a clinical stage biopharma company developing the first drug regimen to treat severe bipolar depression in patients with Acute Suicidal Ideation and Behavior (ASIB), announced that it has signed a Cooperative Research and Development Agreement (CRADA) with the U. S. Department of Veterans Affairs, as represented by the Michael E. DeBakey VA Medical Center in Houston, TX and the Houston VA Research & Education Foundation, Inc. The collaboration also includes Baylor College of Medicine, in Houston, TX. NeuroRx is developing a sequential treatment regimen of NRX-100 (ketamine) and NRX-101 (a proprietary formulation of d-cycloserine / lurasidone), for the treatment of severe bipolar depression in patients with Acute Suicidal Ideation & Behavior (ASIB). The FDA awarded FAST TRACK designation to this investigational drug regimen in September, 2017. NeuroRx has now signed agreements with three clinical trial centers, including one with the University of Alabama, Birmingham. Patient enrollment will begin shortly. The company is in active discussions with additional sites with which it expects to form contracts in early 2018.

There currently is no approved drug therapy for bipolar depression in patients with Acute Suicidal Ideation and Behavior (ASIB); the only FDA-approved treatment is electroconvulsive therapy (ECT). In fact, most antidepressants carry a warning about their potential for increasing the risk of suicide.

"A relatively high proportion of individuals with bipolar disorder attempt suicide in their lifetime, yet patients with Acute Suicidal Ideation and Behaviors have been excluded from virtually all clinical studies," said Sanjay J. Mathew, M.D., Professor in the Menninger Department of Psychiatry and Behavioral Sciences at Baylor College of Medicine. "There is a tremendous unmet need to develop rapid-acting and life-saving new interventions for these individuals, including many veterans and active-duty military personnel. This groundbreaking clinical trial is of critical importance to our field."

"We are delighted to have such leading psychiatric centers participate in our study," said Jonathan Javitt, M.D., M.P.H., NeuroRx Chief Executive Officer. "New research indicates that suicidality has biological underpinnings, which we believe our treatment regimen could potentially address."

### *About Bipolar Depression and Acute Suicidal Ideation & Behavior*

Bipolar disorder, which affects 5.7 million Americans, is characterized by significant changes in mood, from mania or hypomania, to depression, often quite severe. The depressive phase, which is called "bipolar depression," can trigger suicidal thoughts and behaviors. Standard-of-care consists of hospitalized observation and electroconvulsive therapy (ECT). Unfortunately, most commonly-used antidepressants bear an FDA-mandated warning label identifying their potential to increase the risk of suicide.

Each day, approximately 100 Americans, and more than 2,100 people worldwide, end their lives by suicide, according to American Foundation for Suicide Prevention (AFSP) and the World Health Organization (WHO). Although only 10% of all people with depression have bipolar depression, NeuroRx estimates that bipolar depression accounts for nearly half of all suicides each year. Estimates indicate that 50% or more of individuals

with bipolar disorder attempt suicide and that 11% or more succumb to suicide.

#### *About NRX-100 / NRX-101*

NRX-101 is a patented, oral, fixed-dose combination of two FDA-approved drugs: d-cycloserine, a N-methyl-D-aspartate (NMDA) receptor modulator, and lurasidone, a 5-HT<sub>2A</sub> receptor antagonist. NeuroRx's investigational treatment approach begins with a single dose of NRX-100 (ketamine), an FDA-approved anesthetic, for initial stabilization, followed by approximately six weeks of daily oral NRX-101.

Results from two Phase II clinical studies, involving 26 and 8 patients respectively, have been published in peer-reviewed journals. The first study showed a 50% reduction in symptoms of depression in patients with major depressive disorder, and the second, a 75% reduction in suicidal ideation in bipolar patients. In both studies patients were on background antidepressant therapy and then treated with d-cycloserine, one of the active ingredients in NRX-101.

#### *About Baylor College of Medicine*

Baylor College of Medicine (<https://www.bcm.edu/>) in Houston is recognized as a premier academic health sciences center and is known for excellence in education, research and patient care. It is the only private medical school in the greater southwest and is ranked 21st among medical schools for research, and 8th for primary care, by U.S. News & World Report. Baylor is listed 20th among all U.S. medical schools for National Institutes of Health funding and No. 1 in Texas. Located in the Texas Medical Center, Baylor has affiliations with seven teaching hospitals and jointly owns and operates Baylor St. Luke's Medical Center, part of CHI St. Luke's Health. Currently, Baylor trains more than 3,000 medical, graduate, nurse anesthesia, physician assistant and orthotics students, as well as residents and post-doctoral fellows.

#### *About NeuroRx, Inc.*

NeuroRx draws upon 30 years of basic science and clinical expertise in the role of the N-methyl-D-aspartate (NMDA), a receptor that regulates human thought processes, particularly depression and suicidality. The company is privately-funded and led by former senior executives of Johnson and Johnson, Pfizer, Lilly, and Bristol Meyer Squibb.

Learn more at [NeuroRxpharma.com](http://NeuroRxpharma.com).

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Released December 27, 2017

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