



NeuroRx Awarded FDA Fast Track Designation for First Drug Regimen Targeting Suicide in Bipolar Depression

September 6, 2017

Company to present at Rodman and Renshaw Global Investment Conference in New York City on Sept 12, 2017

WILMINGTON, Del., Sept. 6, 2017 /PRNewswire/ -- NeuroRx, a clinical stage biopharma company developing the first oral therapy for Acute Suicidal Ideation and Behavior (ASIB), has been granted Fast Track status by the US Food and Drug Administration for its sequential therapy of NRX-100 (ketamine HCl) followed by NRX-101 (D-cycloserine + lurasidone). The company will shortly begin enrolling patients in a pivotal trial of this sequential therapy targeting patients who are admitted to Emergency Departments with ASIB in bipolar depression.¹

Fast Track Designation is awarded by the FDA to investigational drugs that are deemed by FDA to treat a serious medical condition and for which there is preclinical and/or clinical data to demonstrate that the drug has the potential to address an unmet medical need. Suicidality in Bipolar Depression is a condition for which there is currently no approved drug therapy and for which the only FDA-approved treatment is Electroconvulsive Therapy (ECT).

Jonathan Javitt, M.D., M.P.H., the Company's Chief Executive Officer, will update investors on the Company's progress towards the planned October 2017 initiation of its upcoming clinical trial and recently issued claims at the upcoming Rodman and Renshaw Global Investment Conference, being held on September 11 and 12 at the New York Palace Hotel. In addition, the company is available to conduct one-on-one meetings with registered attendees of the conference. The presentation will be webcast.

<i>Rodman and Renshaw Global Investment Conference Presentation Details</i>	
Date:	Tuesday, September 12
Time:	5:30 PM Eastern Time

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 thoughts of 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 the 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.

About 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_{2a} 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. Findings showed a 50% reduction in symptoms of depression and a 75% reduction in suicidal ideation in bipolar patients who were on background antidepressant therapy and then treated with d-cycloserine, one of the active ingredients in NRX-101.

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.

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1 Details of the clinical trial may be viewed on www.clinicaltrials.gov under the identifier NCT02974010.

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