NeuroRx Announces Phase 2 Data from NRX-101, Initiates Pivotal Study for Severe Bipolar Depression with Acute Suicidal Ideation & Behavior (ASIB)

Wilmington, Delaware– Sept 4, 2018 -- NeuroRx, a clinical stage biopharma company developing NRX-101, the first oral therapy for **Severe Bipolar Depression with Acute Suicidal Ideation & Behavior (ASIB)**, announced today initial top-line data from the Phase 2 STABIL-B trial.

The STABIL-B study is a company-sponsored Phase 2 clinical trial to test sequential therapy of NRX-100 (ketamine) followed by oral NRX-101 (a fixed dose combination of D-cycloserine, an NMDA antagonist, and lurasidone, a D2-5HT2A antagonist, compared to best available therapy (lurasidone alone). The study enrolled 20 patients who presented for emergency care with severe bipolar depression and acute suicidal ideation. Except for a change in one of the rating scales, its design is similar to NeuroRx's phase 2b/3 pivotal protocol approved under a Special Protocol Agreement (SPA) with FDA

Though not powered for efficacy, and in spite of the limited number of enrolled patients, the STABIL-B study has yielded encouraging data. Analysis of top-line data for maintenance of remission of depressive and suicidal symptoms, and prevention of relapse, demonstrated that the drug was well tolerated with no serious adverse events or discontinuations for side effects. Statistically-significant differences were seen between the NRX-101 and lurasidone groups and will be presented at an upcoming scientific conference.

"The STABIL-B Study validates our pivotal study design and statistical analysis plan for the pivotal efficacy study," said Jonathan Javitt, MD, MPH, CEO and Chairman of NeuroRx. To our knowledge, this is the first time that acutely suicidal patients with bipolar depression were successfully and safely enrolled in an FDA-regulated clinical trial. While there have been more than 120 drugs developed to treat major depression, only three are indicated for use in bipolar depression, and none is approved for patients at acute risk of suicide. For decades, patients at risk for suicide have been excluded from virtually all antidepressant clinical studies. In fact, currently-available drugs bear a warning label regarding increased risk of suicide."

NeuroRx has now initiated a Phase 2b/3 pivotal study for the same indication under a Special Protocol Agreement (SPA) with FDA.

The FDA awarded Fast Track Designation to NeuroRx's sequential therapy one year ago. In April 2018 the FDA additionally granted a Biomarker Letter of Support to NeuroRx for NRX-101, along with the Special Protocol Agreement.

NRX-101 was invented by Daniel Javitt, PhD, MD, a Professor of Psychiatry at Columbia University, who first highlighted the importance of the NMDA

receptor in psychiatric conditions in 1989. “In developing our clinical roadmap, we decided to start with suicidal bipolar depression because this is the largest unmet medical need in psychiatry,” said Dr. Javitt. “While only 10% of patients with depression have bipolar disease, they account for up to 40% of those who commit suicide. The only FDA-approved treatment for their condition remains electroconvulsive therapy.”

In 2016, the American Psychiatric Association Task Force on Novel Biomarkers and Therapeutics identified D-Cycloserine as the only promising orally-active rapid-acting antidepressant on the horizon. While this is the first industry-sponsored study to validate the potential effectiveness of D-cycloserine, its findings mirror those of 3 previously-published peer-reviewed academic studies.

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 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). Individuals who suffer from bipolar depression are at far greater risk of suicide than those with major depressive disorder and are believed to represent between 25% and 40% of the 45,000 who end their lives each year in the United States. 11%-20% of those diagnosed with bipolar disorder are believed to take their lives at some point. Overall, suicide has become a national epidemic and is the 10th leading cause of death in the United States.

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-HT2a receptor antagonist. D-cycloserine has now shown activity against depression, on top of standard antidepressant therapy in four clinical studies, and has also shown an effect on suicidality in some of these studies. NRX-101 is designed to address bipolar depression with suicidal ideation, an indication for which there is no currently approved drug and for which the only FDA-approved treatment remains electroconvulsive therapy (ECT). NeuroRx was granted Fast Track designation by the US FDA for this indication in August 2017.

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 &Johnson, Pfizer Inc, and Eli Lilly and Company. NeuroRx's Board of Directors and Advisors includes Hon. Sherry Glied, former Assistant Secretary for Planning and Evaluation Department of the US Health and Human Services; Chaim Hurvitz, former President, TEVA International Group; Wayne Pines, former Associate Commissioner of the United States Food and Drug Administration, and Daniel Troy, former Chief Counsel to the United States Food and Drug Administration.

Learn more at NeuroRxpharma.com.

Contact:

Investor Relations:
Brian Korb
Solebury Trout
+1-917-653-5122
bkorb@troutgroup.com

Media Relations:
Deanne Eagle
Planet Communications
+1-917-837-5866
deanne@planetcommunications.nyc