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NeuroRx solidifies Intellectual Property Position - receives notice of Allowance by US Patent Office

Company with research operations in US and Israel seeks to develop first-in-class drug to decrease the risk of suicide in those suffering from depression

WILMINGTON, Del. and TEL AVIV, Israel, Oct. 18, 2016 /PRNewswire/ -- NeuroRx, a clinical-stage pharmaceutical company developing NRX-101 (CycluradTM), a first-in-class potentially breakthrough oral drug for the treatment of Acute Suicidal Ideation in Bipolar Depression (ASIBD), has received a notice of allowance from the U.S. Patent Office relating to its filing #14/844,021 for the *Composition and Method for Treatment of Depression and Psychosis in Humans*.

The allowed claim relates to D-Cycloserine's ability to block the symptom of akathisia caused by lurasidone, a drug that is indicated for the treatment of patients with bipolar depression. D-Cycloserine – which exhibits NMDA modulatory effects at the selected doses - is one of the components in NRX-101. Akathisia is a symptom associated with suicidal behavior, and a known side effect of many antidepressants. NeuroRx is also pursuing several other patent claims around the world. The company is represented by two well-known global Intellectual Property firms: JMB Davis Ben-David (Jerusalem, Israel) and Kirkland Ellis (New York, USA).

The patent's inventor, Daniel Javitt, Ph.D., M.D., serves as Professor of Psychiatry at Columbia University and is the Chair of NeuroRx's Scientific Advisory Board. Prof. Javitt has been a pioneer in unlocking the molecular basis of psychiatric conditions over the past 25 years and has published more than 250 scientific works in the field.

According to Jonathan Javitt, M.D., MPH, NeuroRx's CEO, "The patent supports the intended clinical use and commercial positioning of CycluradTM. This first allowance also speaks to the innovative science behind our company, and we look forward to further advancing our intellectual property position around the world with our other filings. This first intellectual property milestone further solidifies the investment thesis for NeuroRx."

NeuroRx is planning to initiate clinical Phase 2b/3 studies for NRX-101 by the end of this year.

According to Prof. Sherry Glied, Ph.D., former Asst. Secretary of Planning and Evaluation at the US Department of Health and Human Services and a national expert on mental health policy, who serves as a director of NeuroRx, "More than 100 Americans lose their lives to suicide every day, and no approved drug has been shown to decrease suicidal ideation among people with bipolar disorder. In fact, currently marketed antidepressants carry FDA warning labels indicating the potential for increased risk of suicide. If NRX-101 proves itself to decrease suicidal ideation while also treating depression, it has the potential to be a first-in-class lifesaving drug."

Learn more at NeuroRxpharma.com.

About Bipolar Depression and Acute Suicidal Crisis

Bipolar depression is a uniquely lethal disease affecting three million Americans. Approximately 100 Americans and more than 2,100 people worldwide with this condition end their lives each day. Although only 10% of the 30 million Americans suffering with depressive disorders have bipolar disorder, patients with bipolar disorder account for up to 67% of all associated suicides. Those with acute suicidal crisis, as classified by FDA-recognized scales, have a 33% chance of death within six months. Of the 5.7 million bipolar disorder patients in the U.S., 15%

or approximately 855,000 will ultimately commit suicide. Despite the nature of acute suicidal crisis, many patients seek medical care or are brought to care by families and physicians. Yet, there is no currently approved therapy for the treatment of acute suicidal crisis and most commonly used antidepressants bear an FDA-mandated warning label identifying the potential to trigger suicide. No drug is currently approved for suicidal ideation for bipolar depression; in fact, patients with risk of suicide have been excluded from clinical studies.

About NRX-101 (Cycluradᵀᴹ)

NRX-101 (CycluradTM) is a potential rapid-onset and sustained treatment regimen for Acute Suicidal Crisis associated with Bipolar Depression (ASIBD). The treatment, which is currently investigational and not approved for sale, is a proprietary, 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. NeuroRx's investigational treatment approach begins with a single dose of ketamine, an FDA approved anesthetic, 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 demonstrate more than a 50% reduction in symptoms of depression and a 75% reduction in suicidal ideation in bipolar patients treated with D-cycloserine, one of the components in NRX-101.

About NeuroRx, Inc.

NeuroRx, Inc., is a privately funded, clinical stage pharmaceutical company that is developing NRX-101 (Cyclurad™), the first oral therapeutic that aims to treat suicidal crisis associated with bipolar disorder. The company is built upon 30 years of basic science and clinical expertise in understanding the role of the brain's N-methyl-D-aspartate (NMDA) receptor in regulating human thought processes in general and in regulating depression and suicidality in specific. NeuroRx expects to initiate a Phase II/III clinical trial of NRX-101 (Cyclurad™) in combination with ketamine for the treatment of acute suicidal crisis in bipolar depression in late 2016.

Media Kit: http://bit.ly/1Z83bCT

Contacts	
Media:	Investor Relations:
Pascale Communications, LLC	MDM Worldwide Solutions
Marybeth Cale	David Zazoff
+1-845-750-3763	+1-212-643-0417
marybeth@pascalecommunications.com	dzazoff@mdmworldwide.com

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