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NeuroRx Initiates Pivotal Study for NRX-101, a Breakthrough Designation Therapy Targeting Suicidal Bipolar Depression

Pivotal study will test novel, oral antidepressant in maintaining remission from Severe Bipolar Depression with Acute Suicidal Ideation & Behavior following initial stabilization with ketamine

PHILADELPHIA, July 9, 2019 /PRNewswire/ -- NeuroRx, Inc., a clinical stage biopharma company focused on development of drugs targeting depression and suicidality, announced today that it has initiated a pivotal Phase 2b/3 study for NRX-101 for the treatment of patients with Severe Bipolar Depression and Acute Suicidal Ideation and Behavior (ASIB). NRX-101 has been granted Breakthrough Therapy Designation and Fast Track Designation by the US Food and Drug Administration (FDA). 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).

The pivotal trial design is based on a Special Protocol Agreement (SPA) with the FDA and is similar to the design of the Company's Phase 2 study, STABIL-B, which demonstrated a statistically significant and clinically meaningful difference in suicidal bipolar depression in a head-to-head study between NRX-101 and lurasidone, the standard of care medication. The Phase 2b/3 study will enroll approximately 140 patients with Severe Bipolar Depression and ASIB who are stabilized following a single IV infusion of ketamine. Study participants will be randomized to receive either NRX-101 or lurasidone for six weeks. The primary endpoint is the reduction of depression as measured by the industry-standard MADRS-10 scale. Suicidality and relapse will be measured and monitored throughout the study as secondary endpoints.

"We are delighted to initiate this study of patients suffering from Severe Bipolar Depression and ASIB at JPS Health Network (JPS) in Fort Worth, Texas. NeuroRx is addressing a life-threatening condition that kills 25,000 Americans each year and for which the only currently approved therapy is ECT, with its known complications. This study is the first to test a potentially life-saving alternative for patients with an unmet medical need.

"The NeuroRx study gives JPS Behavioral Health an opportunity to address an important area of clinical need," said Cindy Claassen, PhD, JPS Behavioral Health Director of Research and Education. "Patients who have bipolar depression and who are suicidal are among the highest risk patients we treat at JPS. In patients with unstable mood, suicidal crises can erupt suddenly and with very little warning—at times leading rapidly to dangerous behaviors. Among existing treatments there is frequently a risk of actually increasing the risk of suicidal behaviors instead of lowering risk."

About Bipolar Depression and Acute Suicidal Ideation & Behavior (ASIB)

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 can trigger suicidal thoughts and behaviors. Currently the only FDA-approved treatment for suicidal bipolar depression is electroconvulsive therapy (ECT), which is shown to increase levels of Glx in the brain. Despite its effectiveness, ECT has a myriad of well-known adverse side effects, including confusion and memory loss. Unfortunately, most currently-approved 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 the 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, an N- methyl-D-aspartate (NMDA) receptor modulator, and lurasidone, an FDA-approved D2/5-HT2a receptor antagonist. 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). NRX-101 has been granted Breakthrough Therapy Designation and Fast Track Designation by the FDA. In addition, NeuroRx has received a Biomarker Letter of Support from the FDA, documenting that the Company had shared evidence of increased glutamine and glutamate (Glx) levels associated with oral administration of D-cycloserine, a phenomenon not seen with serotonin-targeted therapies (SSRI).

About NeuroRx, Inc.

NeuroRx draws upon 30 years of basic science and clinical expertise in the role of N-methyl-D- aspartate (NMDA), a receptor that regulates human thought processes, particularly depression and suicidality, as well as post-traumatic stress disorder (PTSD). The Company is privately funded and led by former senior executives of Johnson & Johnson, Bristol-Myers Squibb, Pfizer, Eli Lilly, and Sunovion. NeuroRx's Board of Directors and Advisors includes Hon. Sherry Glied, former Assistant Secretary for Planning and Evaluation, Department of the U.S. Health and Human Services; Chaim Hurvitz, former President, TEVA International Group; Wayne Pines, former Associate Commissioner of the U.S. Food and Drug Administration, and Daniel Troy, former Chief Counsel, U.S. Food and Drug Administration.

About JPS Health Network

JPS Health Network is the publicly supported healthcare system providing medical and behavioral health services to Tarrant County residents. With an annual budget of more than $1 billion, the network includes an acute care hospital, more than 40 primary and specialty care health centers, including 19 public school-based health centers, and the county's only psychiatric emergency center and Level 1 trauma center. Home to 17 clinical residency and fellowship programs, including the largest hospital-based family medicine residency program in the nation, JPS is the largest teaching hospital in the community. Through the course of a year, more than 3,000 students from undergraduate allied health trainees to graduate medical education residents hone their skills at JPS for their future careers. The network's 6,700 team members provide care through more than 1.2 million patient encounters annually. JPS is the only health system in the nation certified to provide care in the areas of Level 1 trauma, stroke, heart attack, sepsis and delirium.

Learn more at NeuroRxpharma.com

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