NeuroRx Receives Special Protocol Agreement (SPA) and Biomarker Letter of Support from FDA for Pivotal Studies of NRX-101 to treat Severe Bipolar Depression in Patients with Acute Suicidal Ideation & Behavior

FDA deems proposed Phase 2b/3 trial adequate to support a regulatory submission.

Wilmington, Delaware– May 7, 2018 -- NeuroRx, a clinical stage biopharmaceutical company developing the first drug regimen to treat Severe Bipolar Depression in patients with Acute Suicidal Ideation and Behavior (ASIB), has been awarded a Special Protocol Agreement letter by the US Food and Drug Administration (FDA) on the design of a Phase 2b/3 study of lead candidate NRX-101, a proprietary formulation of d-cycloserine and lurasidone, in development for this indication. The company received Fast Track designation for NRX-101 in Q3 2017.

NeuroRx also received a Letter of Support from FDA's Center for Drug Evaluation and Research (CDER) encouraging its efforts in the development of Glutamine+Glutamate (Glx) as a pharmacodynamic biomarker for depression. The letter refers to published and unpublished randomized prospective data reviewed by FDA which demonstrate a significant association between clinical symptoms of depression, as measured by traditional rating scales, and levels of brain Glx as measured by magnetic resonance spectroscopy. Furthermore, peer-reviewed studies have shown that intravenous ketamine and oral d-cycloserine, both NMDA blocking drugs, may result in increased Glx, an effect that has not been observed in drugs targeting the serotonin pathway. The letter of Support recognizes that the development of Glx as a pharmaco-dynamic biomarker for depression clinical trials could provide an objective measure to complement currently used patient-focused symptom assessments.

The company also announced that its medical affairs department will meet with physicians interested in participating in upcoming clinical trials at the American Psychiatric Association Annual Meeting, May 6-9, in New York, NY, at booth 1408.

"We are delighted to have reached an agreement with the FDA on the SPA, as well as to have received a Letter of Support, which encourages further investigation of Glx as a biomarker in depression," said Jonathan Javitt M.D., M.P.H, Chief Executive Officer of NeuroRx. "These two significant accomplishments further solidify our development path for what could be the first Glx-targeted antidepressant. We look forward to initiating our Phase 2b/3 clinical trial in the third quarter of this year."

About Special Protocol Assessments

As stated in FDA guidance[1], Special Protocol Assessment (SPA) is a process in which sponsors may ask to meet with FDA to reach agreement on the design and size of certain clinical trials to determine if they adequately address scientific and

[1] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm498793.pdf

regulatory requirements for a study that could support marketing approval. An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval.

Currently, a small minority of drugs in clinical development follow the SPA pathway.

About the FDA Biomarker Program

The FDA Biomarker Program was implemented as part of the 21st Century Cures Act and is designed to help sponsors work with FDA to develop clinical biomarkers that may have potential as Drug Development Tools. For more information, see https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/default.htm.

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). Although only 10% of all people with depression have bipolar depression, NeuroRx estimates that bipolar depression accounts for nearly half of all 45,000 suicides in the U.S. each year. Estimates indicate that 50% or more of individuals with bipolar disorder attempt suicide and that 11% or more succumb to suicide.

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 bear a warning about the potential for increased risk of suicide. 50%-80% of individuals with bipolar depression attempt suicide over their lifetime, and approximately 11% succumb to suicide. NeuroRx currently is the only pharmaceutical company pursuing a clinical development program for depression with ASIB in the bipolar population.

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-HT2a 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, were 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 NeuroRx, Inc.

NeuroRx is a clinical stage, small molecule pharmaceutical company developing novel therapeutics for the treatment of central nervous system disorders. The company 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-Myers Squibb.

Learn more at Neurorxpharma.com.

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