NeuroRx Provides Clinical Development Update for Cyclurad™, a Novel Treatment for Acute Suicidal Crisis in Bipolar Disorder

IND for Phase II/III Trial of Cyclurad to be Filed in Q1 2016; Manufacturing Agreement in Place to Support Study

NeuroRx Announces Key Personnel Additions To Support Cyclurad Development

Wilmington, DE, December 16, 2015 – NeuroRx, a clinical stage pharmaceutical company developing novel therapeutics for the treatment of central nervous system disorders, today announced its plans for advancing Cyclurad™, the company's lead drug candidate, into a Phase II/III clinical trial for the treatment of acute suicidal crisis associated with bipolar depression. The company intends to file an investigational new drug (IND) application with the United States Food and Drug Administration (FDA) for the planned study in the first quarter of 2016 and expects to initiate the trial during the first half of 2016. In preparation for the planned clinical trial initiation, NeuroRx has established a partnership with WuXi Apptec through which WuXi will formulate and manufacture the Cyclurad required for the study. Additionally, the Company is in the final stages of selecting a contract research organization for the Phase II/III trial.

"There is a clear and urgent need for an effective treatment for acute suicidal crisis in bipolar depression, which according to the World Health Organization claims the lives of more than 2,100 individuals around the world each day. We believe that clinical data generated to date on the combination of ketamine and Cyclurad's drug components, while still in proof of concept stage, suggest that NeuroRx's approach can potentially prolong the well-established therapeutic impact of ketamine without the negative side effects in suicidal bipolar patients," said Professor Daniel Javitt, M.D., Ph.D., who chairs NeuroRx's scientific advisory board.

"It is also important to note that D-cycloserine, one of the active ingredients in Cyclurad, has been identified by the American Psychiatric Association Task Force on Novel Biomarkers and Therapeutics as one of the most promising clinical-stage drugs for treating depression by modulating the NMDA receptor. With these considerations in mind, we have a singular focus on advancing the development of Cyclurad, the first oral therapeutic for the treatment of suicidal crisis associated with bipolar disorder, as rapidly as possible. We anticipate initiating our planned Phase II/III trial in the coming year," said Jonathan Javitt, M.D., chief executive officer of NeuroRx.

In additional corporate news, NeuroRx today announced the appointment of several highly-regarded pharmaceutical industry leaders to key board and management team positions. Each of these experts is expected to contribute significantly to the ongoing clinical advancement of Cyclurad. These appointments include:

Hon. Sherry A Glied, Ph.D., Board of Directors

Dr. Glied, whose principal areas of research are in health policy reform and mental health care policy, was named Dean of New York University's Robert F. Wagner Graduate School of Public Service in 2013. From 1989-2013, Dr. Glied was professor of health policy and management at Columbia University's Mailman School of Public Health and served as chair of the department of health policy and management from 1998-2009. In 2010, Dr. Glied was confirmed by the U.S. Senate as Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services, serving in that capacity from July 2010 through August 2012. She had previously served as senior economist for health care and labor market policy on the President's Council of Economic Advisers in 1992-1993, under Presidents Bush and Clinton, and participated in the Clinton Health Care Task Force.

Philip T. Lavin, Ph.D., Chief Methodologist

Dr. Lavin is a highly-respected biostatistician with more than 30 years of experience supporting the design and analysis of clinical trials. Previously, he was a member of the biostatistics faculty at the Harvard School of Public Health and a member of the Department of Surgery at Harvard Medical School where he was affiliated for over 25 years. He co-founded Boston Biostatistics in 1983, a company now known as Aptiv Solutions. During his career, Dr. Lavin has served as lead biostatistician for 50 FDA approvals, including 38 PMAs, more to date than any other biostatistician. He has also served as a Special Government Employee for 30 years where he has advised FDA on complex statistical and policy issues.

Richard C. Siegel, Ph.D., Executive Vice President of Drug Development and Manufacture

Dr. Siegel brings extensive expertise in both technical and strategic aspects of early and late stage drug development. His experience includes process development and manufacture of small molecule drugs, monoclonal antibodies, therapeutic proteins and conjugates, peptides, cellular products and oligonucleotides. During his career, Dr. Siegel has held a number of high-level drug development and manufacturer positions within the Johnson & Johnson family of companies. These include Vice President of R&D and Global Head of Portfolio Management at Janssen Research and Development.

About Bipolar Depression and Acute Suicidal Crisis

Bipolar depression is a 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 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 onset. 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.

About Cyclurad™

Cyclurad™ is being developed as a rapid-onset and sustained treatment for acute suicidal crisis associated with bipolar depression. Cyclurad combines D-cycloserine, an 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 Cyclurad. Peer-reviewed and published results from two Phase II clinical studies demonstrate a significant decline in symptoms of depression following administration of D-cycloserine. Findings from one of these studies found that bipolar patients who were already receiving a 5-HT2a antagonist demonstrated more than a 50% reduction in symptoms of depression and a 75% reduction in suicidal ideation when ketamine and D-cycloserine were added to their treatment regimen. Cyclurad is being developed as a convenient, oral, fixed-dose combination of an 5-HT2a antagonist and D-cycloserine, to be administered following a single dose of ketamine.

About NeuroRx, Inc.

NeuroRx, Inc. is a clinical stage pharmaceutical company that is developing Cyclurad™, the first oral therapeutic for the treatment of 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 Cyclurad in combination with ketamine for the treatment of acute suicidal crisis in bipolar depression during the first half of 2015. More information at www.neurorxpharma.com

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