NeuroRx announces initiation of Israel-based Phase 3 research for treatment of Acute Suicidal Ideation and Behavior in Bipolar Depression

Tel Aviv, Israel – May 22, 2017 -- NeuroRx, a Gold Sponsor of the MIXiii, developing the first drug therapy for **A**cute **S**uicidal **I**deation and **B**ehavior (ASIB) in Bipolar Depression, announces the initiation of Phase 3 research in Israel, with the support of the US Food and Drug Administration (FDA). NeuroRx met with the FDA Division of Psychiatry Products along with the Director of the FDA Office of Drug Evaluation 1 and the Deputy Director of the FDA Center for Drugs in a type B meeting. FDA and NeuroRx discussed the specific advantages of phase 3 drug development research in Israel and NeuroRx secured FDA's support for inclusion of Israel as a study site for its phase 3 clinical trials of its treatment regimen. These studies will be conducted under Helsinki protocol and license from Israel's Ministry of Health, in addition to FDA oversight.

NeuroRx was awarded First Prize in the IATI 2016 Annual Startup Competition at the BIOMED Conference last year. In the subsequent year, NeuroRx has organized its Israel-based R&D subsidiary, with leadership from former Teva executives and seasoned Israeli Clinical Research Associates. The Principal Investigator of the planned phase 3 trial will be Prof. Mark Weiser, Chairman of Psychiatry at Tel Hashomer Medical Center and NeuroRx's medical director will be Dr. Maya Halperin, former Medical Director of Teva, Israel.

In addition to this advance in NRX-100/101 combined therapy for ASIB in Bipolar Depression, Prof. Daniel Javitt, Chairman of NeuroRx's Scientific Advisory Board, will shortly be releasing its preclinical efficacy results for NRX-101 in the treatment of Post-traumatic Stress Disorder (PTSD) at the upcoming invitation-only PTSD Summit co-sponsored by the US Department of Defense and the US Department of Veterans Affairs. In the next few months, NeuroRx will be initiating Phase 2 research in treatment of PTSD in Israel, led by Dr. Eyal Fruchter, Head of Psychiatry at Rambam Medical Center and former Chief Psychiatrist of the IDF.

"We are enormously gratified by the support we have received from Israel Biomed through its Startup Competition and are delighted to be initiating Phase 3 research in Israel with the support of leading members of Israel's medical community," said Prof. Jonathan Javitt, MD, MPH, founder and CEO of NeuroRx. "I know that my dear friend, Eli Hurvitz z"l, the father of Israel's pharmaceutical industry would be very pleased that the US FDA has increasingly recognized Israel as a proper venue for phase 3 research into life-saving cures for humanity's most challenging illnesses."

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

Bipolar disorder, which affects more than 50 million people worldwide, is characterized by significant changes in mood, from mania or hypomania, to depression, often quite severe. The depressive phase, which is called "bipolar depression" and is distinct from the unipolar depression of major depressive disorder, can trigger thoughts of suicide (suicide ideation). For some patients, these thoughts can become strong, creating an urge to develop a plan and/or act upon them, making **A**cute **S**uicidal **I**deation and Behavior (ASIB) in bipolar depression a uniquely lethal disease.

Many patients do seek medical care, or are brought to care by families and physicians, yet there is no approved medicine for the treatment of acute suicidal crisis Standard-of-care consists of hospitalized observation and electroconvulsive therapy (ECT). In fact, most commonly-used antidepressants bear an FDA-mandated warning label identifying the potential to increase the risk of suicide. Studies show that patients are at continued high-risk for suicide after hospitalization for an attempt or suicide ideation.

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). NeuroRx estimates that more than half of all suicides may be related to bipolar disorder.

About NRX-101

NRX-101 is a rapid-onset and sustained oral treatment regimen, currently in an FDA-approved phase 2b/3 pending clinical trial for **A**cute **S**uicidal **I**deation and **B**ehavior (ASIB) in patients with bipolar depression.[1] The treatment, 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, one-time dose of ketamine for rapid stabilization, followed by approximately six weeks of daily oral NRX-101. Preclinical studies have demonstrated an antidepressant effect comparable to market-leading antidepressants, without the akathisia that occurs in 15% of clinical subjects given standard antidepressants. Peer-reviewed results from two Phase II proof-of-concept studies showed a 50% reduction in symptoms of depression and a 75% reduction in suicidal ideation in patients with bipolar and treatment-resistant depression. Initial peer-reviewed studies measuring brain chemical changes in neurotransmitters (Glx) using magnetic resonance spectroscopy (MRS) have demonstrated beneficial brain chemistry changes that meet or exceed those reported for electroconvulsive therapy (ECT), without the damaging side effects of ECT.

[1] https://clinicaltrials.gov/ct2/show/NCT02974010

About NeuroRx, Inc.

NeuroRx, Inc., is a clinical-stage biopharmaceutical company focused on developing first-in-class oral therapies for Acute Suicide Ideation & Behavior (ASIB). Lead product, NRX-101, a dual-targeted NMDA/5-HT_{2A} combination therapy, has received FDA approval to commence a Phase 2b/3 clinical trial for the treatment of ASIB in bipolar depression, the depressed phase of bipolar disorder. The multicenter, 120 patient, study is expected to commence enrollment shortly.

NeuroRx draws upon 30 years of basic and clinical science in the role of the N-methyl-D-aspartate (NMDA), a receptor that regulates human thought processes, particularly depression and suicidality. The company has developed the first NMDA/5-HT_{2A} dual-targeted approach to treatment of depression, a patented scientific advance that has the potential to overcome limitations of previous generations of antidepressant drugs. The NMDA class of drugs, including ketamine, was recognized as having the potential to treat depression decades ago, but has never developed because of propensity to cause hallucination and other side effects. Similarly, the serotonin pathway (SSRI, SNRI, etc.) antidepressants are contraindicated in suicidal patients because of their propensity to cause akathisia, a side effect known to be associated with suicidal behavior. NeuroRx scientists have demonstrated, in preclinical and early clinical studies, that combining NMDA and 5-HT2A antagonist agents in the same drug achieves an antidepressant effect that is comparable to that of leading antidepressants, while also blocking akathisia and reducing suicidal ideation in pre-clinical and clinical studies. NeuroRx's rapid drug development platform is enhanced by the discovery that the antidepressant effect of NeuroRx compounds is closely correlated with beneficial changes in brain chemistry, which can be measured non-invasively by magnetic resonance spectroscopy.

NeuroRx was founded by Drs. Jonathan and Daniel Javitt. Jonathan is an Adjunct Professor of the Johns Hopkins School of Medicine and an Alumnus of Merit of the Harvard School of Public Health who has 30 years of experience in development of life-saving drugs. He has served as a White House Health Advisor in three Presidential Administrations and been a founder of six healthcare startups with public exits. Daniel is a Professor of Psychiatry at Columbia University who first discovered the role of the NMDA receptor in psychiatric illness and has published more than 300 scientific works in cognitive neuroscience that have been cited by more than 30,000. He is the inventor of NRX-101. The Company's executive team includes Dr. Richard Siegel, former Head of the Global Johnson and Johnson drug portfolio and Mr. Robert Besthof, former global VP and commercial lead for Pfizer Neuroscience, Dr. Robert Risinger, former Director of Clinical Studies at Alkermes, and Mr. Wayne Pines, former Associate Commissioner of the US Food and Drug Administration.

Learn more at NeuroRxPharma.com.

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