

Overview

NeuroRx is an emerging clinical stage pharmaceutical company founded by Jonathan C. Javitt, MD, MPH. It was the winner of the recent 2016 IATI Biomed start-up competition in Tel Aviv, Israel. Its operations are located in the USA and Israel.

Their lead development drug candidate, Cyclurad™, could be the first oral therapeutic indicated for **Acute Suicidal Ideation / Behavior (ASIB)** in Bipolar Depression. It is still in the development phase, hence, not approved for use. Finding new medicines is a very high unmet need because, to date, patients at risk for suicide have been excluded from clinical trials for depression.

The Statistics: Bipolar Disorder and Suicide

In the United States, more than **100** people commit suicide every day; **20-40** of those may be due to acute suicidal crisis associated with bipolar disorder (ASIB).

2-3 million Americans suffer from bipolar depression

1/5 bipolar patients will attempt suicide over a period of 5 years*. Patients with Bipolar Depression are **2x** more likely to attempt suicide than with other forms of depression**.

* Holma, K, Haukka J, *Bipolar Disorders* 2014; 16: 652-661

** Chen YW, Dilsaver SC.. *Biol Psychiatry*. 1996;39:896-899.



There is a **1/3** chance of death among those with acute suicidal crisis, as classified by FDA-recognized scales, within six months of onset.



1/5 Bipolar Disorder patients will attempt suicide over a 5-year period



Although only 10% of the 30 million Americans suffering with depressive disorders have bipolar disorder, patients with bipolar disorder may account for **60%** of all suicides.



Key Risk Factors Associated with Suicide in Bipolar Patients

1. Ayal Schaffer et. al., *Australian & New Zealand J'l. of Psych.* 2015
2. Pompili, M.; *Neuropsychiatric Disease and Treatment* 2008
3. Goldstein, T.R.; *Arch Gen Psychiatry* . 2012 November ;
4. Tidemalm, D.; *PLOS ONE* www.plosone.org, 1 April 2007

The Science Behind NRX-101 (Cyclurad™)

A breakthrough in research suggests that the chemical target for suicidality in bipolar depression may be localized in the NMDA receptor. As the gateway for new thoughts being produced in the brain, the activity of the NMDA channel is critical to mental health. It has been established that just lowering depression does not directly correlate with decreased suicidal ideation.

- When there is excessive NMDA activity, the rate at which new thoughts are generated (ideation), and the speed of thought itself, are slowed. People tend to ruminate on just a few self-destructive and negative thoughts.
- When the NMDA channel is blocked, thoughts are generated rapidly, which can lead to hallucinations..

Investigational Treatment
Not approved by FDA

About NRX-101 (Cyclurad™)

NRX-101 (Cyclurad™) is the first oral therapeutic in development for the treatment of Acute Suicidal Ideation/Behavior (ASIB) associated with Bipolar Depression. It is a proprietary, oral-fixed dose combination of two FDA-approved drugs:

- D-cycloserine
- Lurasidone

The investigational treatment approach begins with single dose of ketamine*, followed by six weeks of daily oral NRX-101. Phase 2b/3 clinical trial expected to begin in early 2017.

NRX-101 treatment approach is expected to offer a rapid-onset induction with ketamine and oral outpatient therapy to extend ketamine's anti-depressant /anti-suicidal effects.

* FDA approved anesthetic for surgeries, not approved for treatment of depression or suicidal ideation

For More Information:

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Patient Population and Notable Items

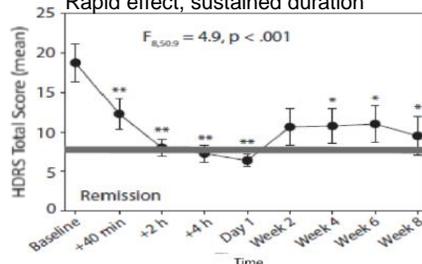
NRX-101 (Cyclurad™) will be a prescription medicine for Acute Suicidal Ideation/Behavior (ASIB) in bipolar depression patients, and will allow treatment on an outpatient basis.

NRX-101 is not expected to be a controlled substance.

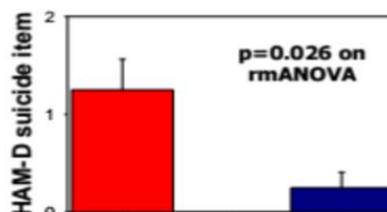
NRX-101 should extend Ketamine's antidepressant / anti-suicidal effects, which will be administered in a clinic setting.

Ketamine followed by NRX-101 - Phase IIa, Treatment Resistant Bipolar Depression

Rapid effect, sustained duration



Rapid ↓ 50% depression
Sustained over 56 days



Rapid and sustained ↓ 75%
in suicidality at 8 weeks
N=8, no control group

Small sample
Statistically significant results