NRx Pharmaceuticals Announces FDA Grant of Expanded Access Protocol for Use of D-Cycloserine-based NRX-101 for Augmentation of Transcranial Magnetic Stimulation in the Treatment of Depression

June 22, 2026

- D-Cycloserine (DCS) has been reported to augment the effect of Transcranial Magnetic Stimulation (TMS) in remission from depression and suicidality in several published clinical studies.
- NRx Pharmaceuticals is developing NRX-101, a fixed dose combination of DCS+lurasidone for the augmentation of TMS and has initiated a pivotal clinical trial in both civilian and military treatment facilities.
- The Expanded Access protocol is designed to make NRX-101 available under FDA-authorized compassionate care mechanisms for patients who cannot access the pivotal trial.
- Physicians who wish to provide NRX-101 in association with accelerated TMS for patients with Treatment-Resistant Depression may register at www.nrxpharma.com/EAP

WILMINGTON, Del., June 22, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a biopharmaceutical company that focuses on neuroplastic therapies for depression, PTSD, and related conditions, today announces the approval by FDA of an Intermediate Population Expanded Access Protocol for the use of NRX-101, a fixed dose combination of D-cycloserine (DCS) and lurasidone for the augmentation of accelerated Transcranial Magnetic Stimulation (TMS). Expanded Access Protocols are part of FDA's compassionate care approach to making investigational drugs available to patients with serious or life-threatening medical conditions[1].

In recent years, there have been multiple scientific reports which suggest that DCS may enhance the effectiveness of TMS in treating Treatment Resistant Depression and Suicidality.[2,3] DCS has been demonstrated to have potent neuroplastic effects in laboratory studies. Neuroplasticity is the scientific term for the creation of new connections or synapses between brain cells and is believed to be key to the reversal of depression and suicidality. The Company has announced initiation of a pivotal clinical trial (the Synaptic Plasticity Augmented Rapid Circuit Stimulation (SPARC-TMS) study) to assess the effect of NRX-101 in augmenting TMS to achieve remission from Depression and Suicidality in patients being treated with mechanism-guided augmentation of neuronavigated robotic TMS, a study that will be conducted in both civilian and military treatment facilities.

While the use of DCS is increasingly discussed and adopted within the professional community based on Real World Evidence, the doses required are below the dose of DCS that is currently marketed and sold for the treatment of tuberculosis (the currently approved indication), which has led to an increasing use of compounded versions of DCS. Compounded drugs are neither supervised nor approved by the US FDA. In the case of DCS, compounding is particularly challenging because the DCS pharmaceutical ingredient is highly susceptible to degradation without special formulation processes. When NRx first developed NRX-101, two years of research and development was required to properly control impurities and achieve long-term stability. Compounded drugs (except those eligible for 503b manufacture, which DCS is not) are not assessed for stability and impurities by compounding pharmacists, who lack the chromatography equipment required for FDA Good Manufacturing Practices (GMP) controls. Accordingly, NRx Pharmaceuticals has elected to make NRX-101 available to physicians and their patients under the Expanded Access Protocol while pivotal clinical trials are underway in an effort to assure that this potentially life-saving drug is immediately available for patients who qualify. Initially, the Company will be charging only for shipping and FDA-required data collection costs, but not for the investigational drug.

"We at NRx deeply appreciate the engagement of the FDA Division of Psychiatry Products and their support of expanded access to regulated and GMP-manufactured D-cycloserine to enhance TMS effectiveness," said Prof. Joshua Brown, MD, PhD, the Company's Chief Medical Innovation Officer. "We look forward to reporting the results of our upcoming pivotal trial, SPARC-TMS, which aims to determine the efficacy of the NRX-101–TMS combination in achieving remission from depression and suicidality in patients with Treatment-Resistant Depression." Dr. Brown serves as Editor-in-Chief of the Transcranial Magnetic Stimulation journal, and as immediate past President of the Clinical TMS Society, and as an Assistant Professor at Harvard Medical School and McLean Hospital.

About NRx Pharmaceuticals, Inc.
NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA receptor platform for the treatment of central nervous system disorders, specifically suicidal depression, chronic pain, and PTSD. The Company is developing NRX-100 (preservative-free intravenous ketamine) and NRX-101, (oral D-cycloserine/lurasidone). NRX-100 has been awarded Fast Track Designation for the treatment of Suicidal ideation in Depression, including Bipolar Depression. NRX-101 has been awarded Breakthrough Therapy Designation for the treatment of suicidal bipolar depression. NRx has filed an Abbreviated New Drug Application (ANDA) and initiated a New Drug Application filing

for NRX-100 for the treatment of suicidal ideation in patients with depression, including bipolar depression.

Notice Regarding Forward-Looking Statements
The information contained herein includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. These statements relate to future events or to the Company's future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. The Company has reported regulatory milestones as they have been achieved but has not predicted the outcome of any future regulatory determination. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond the Company's control and which could, and likely will, materially affect actual results, levels of activity, performance or achievements. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, including uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, and, among other things, liquidity. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at **http://www.sec.gov**. Except as may be required by applicable law, the Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events or otherwise.

For further information:
Brian Korb
Managing Partner, astr partners
(917) 653-5122
brian.korb@astrpartners.com

---

[1] https://www.fda.gov/news-events/public-health-focus/expanded-access

[2] M Cole J, et.al. Efficacy of Adjunctive D-Cycloserine to Intermittent Theta-Burst Stimulation for Major Depressive Disorder: A Randomized Clinical Trial. JAMA Psychiatry. 2022;79(12):1153–1161. doi:10.1001/jamapsychiatry.2022.3255

[3] Vaughn, Donald & Marino, Brooke & Engelbertson, Alex & Dojnov, Aleksandra & Weiss, Nick & Vila-Rodriguez, Fidel & Nanos, Georgine & Downar, Jonathan. (2024). Real-world effectiveness of a single-day regimen for transcranial magnetic stimulation using Optimized, Neuroplastogen-Enhanced techniques in Depression (ONE-D). Transcranial Magnetic Stimulation, 2025; 5. DOI: 10.1016/j.transm.2025.100200