



NRx Pharmaceuticals (Nasdaq: NRXP) to Present Keynote Address on Ketamine Efficacy and Risks at Upcoming Sachs Neuroscience Innovation Forum in San Francisco

January 2, 2024

- *The benefits of ketamine are clear, but so are the risks*
- *Ketamine has now demonstrated clear superiority to placebo and non-inferiority to electroshock therapy in randomized trials encompassing more than 1,000 patients*
- *NRx to file a New Drug Application for ketamine to treat suicidal depression in 2024 in US and EU*

RADNOR, Pa., Jan. 2, 2024 [/PRNewswire/](#) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", (NRx), a clinical-stage biopharmaceutical company today announced that it has been selected to give the keynote address entitled "Ketamine for Suicidal Depression: The Benefits are Clear, But So are the Risks," at the upcoming Sachs Neuroscience Innovation Forum in San Francisco, CA on January 7, 2024. The Company plans to file a New Drug Application for Ketamine in 2024, both in the United States and the European Union in partnership with the Fondation FundaMental of Paris, FR.

"When FDA first granted us Fast Track Designation to develop ketamine as a life-saving drug for the treatment of suicidal depression in 2017, evidence of efficacy was shown in only small clinical trials," said Jonathan Javitt, MD, MPH, Founder, Chairman, and Chief Scientist of NRx Pharmaceuticals. "Ketamine's efficacy was so dramatic that ketamine became a standard of care ahead of the large clinical trials required for drug approval. Ketamine, as expected, now been demonstrated to be dramatically superior to placebo in large clinical trials. What could not be predicted is that ketamine has been shown to be at least as good as (i.e. non-inferior) to electroshock therapy (ECT), and in one trial demonstrated superiority over ECT. The problem is that ketamine is sold only in a 70 year old formulation designed for use in human and veterinary anesthesia and cannot be used in the clinic setting without quasi-legal compounding in a local pharmacy, a practice that FDA has warned against. We have partnered with Nephron Pharmaceuticals to develop a modern, single use, diversion- and tamper-resistant formulation of ketamine. Moreover, we are partnering with psychiatry leaders in the US and Europe to develop a Risk Evaluation and Mitigation Strategy (REMS) program for ketamine that will include training for providers in its safe and proper use."

NRx has advised its shareholders that it has incorporated HOPE Therapeutics, Inc. to carry forward its drug development of ketamine and will be awarding rights in HOPE to existing shareholders together with new investors.

The Keynote presentation will be simulcast; information will be available in the company's website, as well as a question and answer session to be moderated by Bob "Sully" Sullivan of Biz Talk.

About NRx Pharmaceutical

NRx Pharmaceuticals is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal bipolar depression, chronic pain and PTSD. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRx has partnered with Alvogen Pharmaceuticals around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain.

NRx has recently announced plans to submit a New Drug Application for ketamine in the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality.

Cautionary Note Regarding Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management. Actual results could differ materially from those contemplated by the forward-looking statements. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K, as may be supplemented, or amended by the Company's Quarterly Reports on Form 10-Q. Given these risks, uncertainties, and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by these cautionary statements.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

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