Neurolixis Announces Positive Ph2A Proof-of-Concept on NLX-112 in Levodopa-Induced Dyskinesia in Parkinson’s Disease

A New Approach Using a First-in-Class Highly Selective and Efficacious Serotonin 5-HT1A Receptor Biased Agonist

NJ, UNITED STATES, March 20, 2023 /EINPresswire.com/ -- Neurolixis, Inc., a private, clinical-stage company developing innovative drug therapies for the treatment of neurologic and psychiatric disorders with high unmet medical needs, today announced the positive results of its Phase 2A clinical trial with NLX-112 (befiradol), for treatment of levodopa-induced dyskinesias (LID) in Parkinson’s disease (PD). NLX-112, a first-in-kind, highly selective serotonin 5-HT1A receptor activator, met the primary outcome of safety and tolerability and, in addition, showed statistically significant efficacy in reducing LID symptoms in Parkinson’s disease patients.

> We are excited about the positive results of this proof-of-concept study; the findings indicate that NLX-112 can be safely administered to people with PD and alleviates their troublesome LID.”
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> *Prof. Per Svenningsson, Principal Investigator, Karolinska Institute*

Dyskinesia is a common side effect experienced by people with Parkinson's who have been taking levodopa-based medications — a standard treatment for Parkinson's — for several years. Between 40 and 50 percent of people with Parkinson's will experience dyskinesia after just five years of taking levodopa. After ten years of taking the medication, this figure increases to 80 percent. The main medication available to manage dyskinesia is amantadine, which can have challenging side effects and does not work for everyone.

"We are excited about the positive results of this proof-of-concept study," said □□□□. □□□ □□□□□□□□□□□□□, Principal Clinical Investigator at the Karolinska

institute. "The findings indicate that NLX-112 can be safely administered to people with PD and alleviates their troublesome LID. If these findings are confirmed in larger clinical trials, NLX-112 could become a promising new treatment option for this indication."

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"The findings of this latest phase 2a trial of NXL-112's potential to treat LID are exciting for us all to see. Further studies will be necessary for regulatory approval and routine clinical use. But now people with Parkinson's can have hope that a much needed new treatment for LID may be coming to them soon, and know that their support of the Parkinson's Virtual Biotech has made this possible."

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The study (ClinicalTrials.gov ID: NCT05148884) was a randomized, double-blind, placebo-controlled trial conducted at 5 centers in Sweden, and enrolled 27 subjects with troubling LID. Subjects were maintained on a stable dose of levodopa and other anti-PD medications. Study drug dosing was individually up-titrated over 28 days to a maximum of 2 mg/day (1 mg b.i.d.); dosing was kept stable for 14 days (until day 42) and then down-titrated over 14 days. Subjects received a levodopa challenge (150% of regular dose) at day 1 (baseline) and at test days 28 and 42. The primary outcome was safety and tolerability; secondary outcome for efficacy in reducing troublesome LID used the Unified Dyskinesia Rating Scale (UDysRS). Other motor and non-motor

symptoms of PD were also assessed.
22 patients (15 on NLX-112, 7 on PBO) completed the 8-week treatment according to the protocol. Safety was good and did not differ between NLX-112 and placebo groups. Tolerability was favorable, there were no serious adverse events in the NLX-112 group. Beyond meeting the primary outcome of safety and tolerability, NLX-112 also achieved significant reductions in LID scores, whereas placebo group changes were not significant. Full analysis of efficacy measures is underway and will be disclosed in further announcements and at upcoming scientific conferences. Neurolixis plans to advance NLX-112 to a Phase 2B study to further evaluate the drug's efficacy and safety in a larger patient population.

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Neurolixis is a biopharmaceutical company focused on the discovery and development of novel drugs for the treatment of central nervous system disorders with unmet medical needs and sizeable market opportunity, including movement disorders, autism spectrum disorders, depression and pain. Neurolixis is developing a platform of drug candidates based on the concept of serotonin 5 HT1A receptor 'biased agonism' which enables drugs to more precisely target specific brain regions controlling CNS disorders.
NLX-112 is an exceptionally selective and high efficacy serotonin 5-HT1A receptor agonist that shows potent and efficacious anti-dyskinetic properties in rodent, marmoset and macaque models of levodopa-induced dyskinesia. NLX-112 has previously shown favorable safety and tolerance in over 600 subjects during Ph1 and Ph2 trials for other indications but had never been administered to Parkinson's disease patients. NLX-112 is also under study as a potential treatment for spinocerebellar ataxia and essential tremor.
For more information, contact Pim Cerutti, Liberi Group Life Science Business Development & Strategy; pimcerutti@LiberiGroup.com

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Founded by Parkinson's UK in 2017, the Parkinson's Virtual Biotech is now an international programme in partnership between Parkinson's UK and the Parkinson's Foundation in the US. We believe we'll get to a cure faster by joining forces and collaborating. Like other biotechs, The Parkinson's Virtual Biotech uses cutting edge biological and chemical research to come up with new treatments, and testing them in clinical trials. But it's driven by people with Parkinson's, not profit. Collaborative and agile, it adapts successful methods from the business world to deliver new treatments faster. The innovative approach is working. The next treatment is closer than ever, thanks to this groundbreaking global movement to deliver life-changing new treatments in years not decades.

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Parkinson's is the fastest growing neurological condition in the world. Around 145,000 people in the UK have Parkinson's.
We are Parkinson's UK. Here for everyone affected by the condition. Funding research into the most promising treatments, taking us closer to a cure every day. Fighting for fair treatment and better services. Read more facts and statistics.

Further information, advice and support is available on our website, www.parkinsons.org.uk or our free, confidential helpline on 0808 800 0303.

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As the world's largest nonprofit funder of Parkinson's research, The Michael J. Fox Foundation is dedicated to accelerating a cure for Parkinson's disease and improved therapies for those living with the condition today. The Foundation pursues its goals through an aggressively funded, highly targeted research program coupled with active global engagement of scientists, Parkinson's patients, business leaders, clinical trial participants, donors and volunteers. In addition to funding more than $1.75 billion in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. Operating at the hub of worldwide Parkinson's research, the Foundation forges groundbreaking collaborations with industry leaders, academic scientists and government research funders; creates a robust open-access data set and biosample library to speed scientific breakthroughs and treatment with its landmark clinical study, PPMI; increases the flow of participants into Parkinson's disease clinical trials with its online tool, Fox Trial Finder; promotes Parkinson's awareness through high-profile advocacy, events and outreach; and coordinates the grassroots involvement of thousands of Team Fox members around the world.

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