First Patient Dosed in Phase 2a Trial of NLX-112 for the Treatment of L-DOPA Induced Dyskinesia in Parkinson's Disease

NEW JERSEY, USA, November 30, 2021 /EINPresswire.com/ -- Neurolixis, a clinical-stage biopharmaceutical company focused on advancing novel therapies to treat central nervous system disorders, announced today dosing of the first patient in its Phase 2a clinical trial evaluating NLX-112 in Parkinson's disease patients with disabling levodopa-induced dyskinesia (LID). Levodopa is the principal pharmacotherapeutic for Parkinson's disease but can elicit involuntary movements, known as dyskinesia, after several years of treatment. The safe and effective treatment of LID remains a high unmet need in the Parkinson's community.

> "NLX-112 could significantly improve the quality of life of many Parkinson's disease patients for whom dyskinesia prevents them from performing routine daily tasks."
>
> *Prof. Per Svenningsson, MD, PhD*

The investigational drug, NLX-112 (also known as befiradol), acts on the brain's serotonin system, and is a highly specific and efficacious activator of neuronal proteins known as 5-HT1A receptors. Neurolixis has previously shown that NLX-112 exhibits robust anti-dyskinetic activity in preclinical models of Parkinson's disease, without interfering with Levodopa's therapeutic properties. NLX-112 is orally administered and has previously been safely evaluated in over 600 human subjects.

The clinical study at the Karolinska Institute in Stockholm and at four other sites in Sweden, will recruit a total of 24 patients in a double-blind, placebo-controlled, randomized trial. As well as safety, tolerance and anti-LID activity, the study will investigate whether NLX-112 can reduce non-motor symptoms, including depressed mood, pain and disturbed sleep. The leading charities, Parkinson's UK and The Michael J. Fox Foundation (MJFF) joined forces to fund the £1.5m ($2m) trial.

Prof. Per Svenningsson, MD, PhD, Principal Clinical Investigator of the study said:
"We are excited to be testing NLX-112 as a novel treatment for LID. If the striking profile of NLX-112 seen in preclinical models translates to the clinical setting, it could significantly improve the quality of life of many Parkinson's disease patients for whom dyskinesia prevents them from performing routine daily tasks."

Adrian Newman-Tancredi, PhD, DSc, CEO of Neurolixis commented:
"It's great that patient recruitment has now commenced in this proof-of-concept study. Compelling experimental validation points to serotonin 5-HT1A receptors as promising targets for improved treatment of LID. NLX-112 is a first-in-kind drug candidate for this indication and its distinctive pharmacological profile suggests that it may also alleviate some non-motor symptoms of PD. We are grateful to Parkinson's UK and the MJFF for supporting this project."

Arthur Roach, PhD, Director of Research at Parkinson's UK, said:
"We're pleased to be supporting this study which aims to deliver a treatment that is desperately needed by many people living with Parkinson's. It's great that recruitment is now underway as this milestone brings us one step closer to results which could reveal an important new therapy for the millions living with this condition around the world."

Marco Baptista, PhD, MJFF Vice President of Research Programs, said:
"A treatment for dyskinesia would significantly improve quality of life for millions with Parkinson's who experience this common medication side effect. We are proud to partner with Parkinson's UK and Neurolixis and with the study volunteers to advance this therapy in testing."

About Parkinson's disease and Levodopa-induced Dyskinesia
Parkinson's is a degenerative neurological condition, for which there currently is no cure. The main symptoms of the condition are tremor, slowness of movement and rigidity. Levodopa-induced dyskinesia (LID), which can be severely disabling, are involuntary movements that commonly occur in Parkinson's patients after several years of treatment with therapies such as levodopa. The occurrence of LID can limit the dosing of Levodopa, which may result in inadequate control of parkinsonian symptoms.

About Neurolixis, Inc.
Neurolixis is a privately held biotechnology company developing therapies for disorders of the central nervous system. The Company has two clinical programs: NLX-112 targets LID as well as other movement disorders, and NLX-101 is a Phase 1 drug candidate targeting Rett syndrome. NLX-204, a preclinical candidate, targets depression and pain (via non-opioid mechanisms). Further information is available at www.neurolixis.com

About Parkinson's UK
Parkinson's UK is the UK's leading charity supporting those with the condition. Its mission is to find a cure and improve life for everyone affected by Parkinson's through pioneering research, information, support and campaigning. Parkinson's UK is looking for further partners to help it create a portfolio of projects that can attract further investment and take successful projects into the later stages of drug development and trials. For more information visit:
www.parkinsonsvirtualbiotech.co.uk

About The Michael J. Fox Foundation
As the world's largest non-profit 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 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; 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. For more information, visit us on Facebook, Twitter, Web and LinkedIn.

Forward Looking Statement
Except for the historical information contained herein, the matters discussed in this press release are forward-looking statements that involve risks and uncertainties, including: our dependence on third parties for the development, regulatory approval and successful commercialization of our products, the inherent risk of failure in developing product candidates based on new technologies, risks associated with the costs of clinical development efforts, as well as other risks. Actual results may differ materially from those projected. These forward-looking statements represent our judgment as of the date of the release. Neurolixis disclaims any intent or obligation to update these forward-looking statements.

Press Contact:
Adrian NEWMAN-TANCREDI
contact@neurolixis.com
