PharmaTher Announces Successful Completion of Pre-IND Meeting with FDA for the Clinical Development of Ketamine in the Treatment of Parkinson's Disease

TORONTO, Feb. 04, 2021 (GLOBE NEWSWIRE) -- Newscope Capital Corporation (CSE: PHRM) (OTCQB: PHRRF), who through its wholly-owned subsidiary, PharmaTher Inc. ("PharmaTher"), is a specialty life sciences company focused on the research and development of psychedelic pharmaceuticals, announced today the successful completion of a Type B pre-Investigational New Drug ("pre-IND") meeting with the U.S. Food and Drug Administration ("FDA") regarding PharmaTher's clinical development plan and its proposed Phase 2 clinical study for ketamine in the treatment of levodopa-induced dyskinesia in patients with Parkinson's disease ("LID-PD"). Based on the FDA's feedback from the written response meeting, the FDA confirmed that a 505(b)(2) regulatory pathway is acceptable, which allows for the potential to accelerate the clinical development for drug approval.

In addition to responses of several aspects of the nonclinical and clinical development plan, the FDA was supportive of the proposed Phase 2 clinical study and the use of the Unified Dyskinesia Rating Scale score at three weeks as the primary efficacy endpoint. The FDA also recommended to include various efficacy and safety parameters and endpoints in the proposed Phase 2 clinical study to support future pivotal clinical trials, also known as 'registration studies' used by regulatory authorities to evaluate a drug's safety and efficacy for commercial approval.

PharmaTher will proceed to file an IND application in Q1-2021 with the aim to initiate the Phase 2 clinical study in Q2-2021.

"We were very pleased with the outcome of our pre-IND meeting with the FDA as it provided positive guidance to support our clinical development program for ketamine to treat Parkinson's disease patients while also outlining the various safety and efficacy endpoints to be used in the Phase 2 study to support a potential Phase 3 clinical study in the future," said Fabio Chianelli, CEO of PharmaTher. "We have an exemplary clinical and regulatory team that will focus on completing our IND application with the goal to initiate the Phase 2 clinical study in Q2-2021."

The Company has assembled a prolific scientific and clinical team experienced in Parkinson's disease, including Dr. Scott Sherman and Dr. Torsten Falk from the University of Arizona, Dr. Alberto Espay from the University of Cincinnati and Dr. Robert Hauser from the University of South Florida.

Ketamine is an FDA-approved drug with a known safety profile. PharmaTher entered into an exclusive license agreement with the University of Arizona to develop and commercialize ketamine to treat Parkinson's disease and movement disorders.

Study results from preclinical studies and case studies in Parkinson's disease patients from the University of Arizona have shown that low-dose sub-anesthetic ketamine infusion indicates tolerability, safety and the potential of long-term therapeutic benefit to reduce levodopa-induced dyskinesia, improve on time, and reduce depression.[1-5]

Parkinson's disease is a debilitating disorder that affects over 1 million people in the U.S. and more than 7 million people worldwide. There is currently no cure for Parkinson's disease, although some drug combinations are used to treat the disease symptoms. The global Parkinson's disease market is expected to grow from USD $5 billion in 2019 to USD $7.5 billion by the end of 2025 [6] and it is estimated that the potential market opportunity for LID-PD to be over USD $3 billion in the U.S. alone.

About PharmaTher Inc.

PharmaTher Inc., a wholly-owned subsidiary of Newscope Capital Corporation (CSE: PHRM) (OTCQB: PHRRF), is a specialty life sciences company focused on the research and development of psychedelic pharmaceuticals, such as ketamine, for FDA approval to treat mental health, neurological and pain disorders.

Learn more at: **PharmaTher.com** and follow us on **Twitter**, **LinkedIn** and **Facebook**.

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This news release does not constitute an offer to sell or the solicitation of an offer to buy, and shall not constitute an offer, solicitation or sale in any state, province, territory or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state, province, territory or jurisdiction.

References:

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2. *US20190060254A1— Compositions and methods for treating motor disorders.*
3. *Bartlett, et al, 2020. Preclinical evidence in support of repurposing sub-anesthetic ketamine as a treatment for L-DOPA -induced dyskinesia. Experimental Neurology. Volume 333.*
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5. *Sherman, S.J., Estevez, M., Magill, A.B., Falk, T., 2016. Case reports showing a long-term effect of subanesthetic ketamine infusion in reducing L-DOPA-induced dyskinesias. Case Rep. Neurol. 8, 53–58.*
6. *360iResearch 2020.*