



PharmaTher Files FDA Pre-IND Meeting Request for Ketamine in Parkinson's Disease

TORONTO, Dec. 08, 2020 (GLOBE NEWSWIRE) -- PharmaTher Inc., ("PharmaTher" or the "Company"), a wholly-owned subsidiary of Newscope Capital Corporation (CSE: PHRM) (OTC Pink: PHRRF) and a specialty life sciences company focused on the research and development of psychedelic pharmaceuticals, is pleased to announce that it has filed its pre-Investigational New Drug ("pre-IND") meeting request and complete pre-IND briefing documents with the U.S. Food and Drug Administration ("FDA") to support the clinical development of ketamine in Parkinson's disease and to evaluate the proposed Phase 2 clinical study for ketamine in the treatment of levodopa-induced dyskinesia associated with Parkinson's disease ("LID-PD").

"We are pleased to have taken this important step in advancing our ketamine program for Parkinson's disease via the FDA regulatory pathway, which is part of our overall strategy of progressing our novel ketamine prescription-based therapies to treat neurological disorders for FDA approval," said Fabio Chianelli, CEO of PharmaTher. "We look forward to finalizing our Phase 2 clinical study for ketamine in Parkinson's disease and leveraging the pre-IND meeting to unlock additional value in our exclusive FDA-based ketamine programs in depression and pain."

PharmaTher is progressing its patent portfolio of novel ketamine therapies for Parkinson's disease, depression and pain via the FDA regulatory pathway. The pre-IND meeting will provide valuable information to pave the way for the Company to conduct a Phase 2 clinical study in the U.S.

Results from preclinical data and case studies in Parkinson's disease patients 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

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 in the treatment of Parkinson's disease and has filed with the FDA to receive orphan drug designation for ketamine in the treatment of LID-PD.

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.

About Parkinson's Disease

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 2025⁶ 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) (OTC Pink: PHRRF), is a specialty life sciences company focused on the research and development of psychedelic pharmaceuticals. PharmaTher repurposes psychedelic pharmaceuticals, such as FDA-approved ketamine and psilocybin, for FDA approval to treat neurological disorders.

Learn more at: [PharmaTher.com](https://www.pharmather.com) and follow us on [Twitter](https://twitter.com/PharmaTher), [LinkedIn](https://www.linkedin.com/company/pharmather) and [Facebook](https://www.facebook.com/PharmaTher).

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Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.

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This press release contains 'forward-looking information' within the meaning of applicable Canadian securities legislation. These statements relate to future events or future performance. The use of any of the words "could", "intend", "expect", "believe", "will", "projected", "estimated", "potential" and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on the Newscope Capital Corporation's (the "Company") current belief or assumptions as to the outcome and timing of such future events. Forward-looking information in this press release includes information with respect to the development and commercialization of ketamine for neurological disorders, FDA approval, pre-IND meeting, psilocybin and ketamine programs and product developments. Forward-looking information is based on reasonable assumptions that have been made by the Company at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ

materially from those anticipated in the forward-looking information. Given these risks, uncertainties and assumptions, you should not unduly rely on these forward-looking statements. The forward-looking information contained in this press release is made as of the date hereof, and Company is not obligated to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable securities laws. The foregoing statements expressly qualify any forward-looking information contained herein. Factors that could cause actual results to differ materially from those anticipated in these forward-looking statements are described under the caption "Risk Factors" in Company's management's discussion and analysis for the period of August 30, 2020 ("MD&A"), dated October 1, 2020, which is available on the Company's profile at www.sedar.com.

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:

1. [UA Clinical Trial to Repurpose Ketamine for Parkinson's Patients.](#)
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.](#)
4. [Bartlett, M.J., Joseph, R.M., LePoidevin, L.M., Parent, K.L., Laude, N.D., Lazarus, L.B., Heien, M.L., Estevez, M., Sherman, S.J., Falk, T., 2016. Long-term effect of sub-anesthetic ketamine in reducing L-DOPA-induced dyskinesias in a preclinical model.](#)
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.](#)