Pharmather Files for FDA Orphan Drug Designation for Ketamine in Neuropathic Pain

TORONTO, Oct. 27, 2020 -- Pharmather Inc., a wholly-owned subsidiary of Newscope Capital Corporation (“**Pharmather**” or the “**Company**”) (CSE: PHRM) and a specialty life sciences company focused on the research and development of psychedelic pharmaceuticals, is pleased to announce it has filed an application with the U.S. Food and Drug Administration (“FDA”) to receive Orphan Drug Designation (“ODD”) for ketamine in the treatment of Postherpetic neuralgia (“PHN”), a chronic neuropathic pain syndrome resulting from an outbreak of the herpes zoster virus, also known as shingles. According to Persistence Market Research, the global PHN market is expected to be valued at USD $908.4 million by 2026.

"Our FDA orphan drug application for ketamine to treat PHN is complementary to our growing psychedelic drug development pipeline for rare disorders," stated Fabio Chianelli, CEO of Pharmather. "We are focused on building a unique ketamine franchise targeting unmet medical needs such as Parkinson’s disease, depression and pain. We are leveraging scientific and clinical data to advance the development of ketamine through the FDA approval process, as well as carving our niche in the rapidly evolving psychedelic pharmaceuticals market.”

The Orphan Drug Act grants special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). The FDA grants ODD status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. ODD would qualify ketamine for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees.

Proposed Use of Ketamine in PHN

Ketamine is an N-methyl-D-aspartate (“NMDA”) receptor antagonist that has the potential to be a treatment option for PHN or as a secondary treatment option for refractory PHN. There is no single treatment option for PHN that surpasses other therapies. Each patient’s case is somewhat different and typically requires a multi-therapeutic approach whereby therapeutic decisions generally are made based on the patient’s symptoms, age, circumstances, and other medical histories. The available treatments are typically inadequate and suboptimal for the relief of pain because of their local action, long titration periods, inadequate dosing and intolerable side effects that are prevalent in topical and systemic treatments. These outcomes lead to poor patient compliance, switching to other classes of medication and low physician and patient satisfaction. In addition, PHN often becomes refractory to treatment. These all lead ultimately to poor quality of life for those suffering with PHN.

In a PHN study, the use of ketamine supported the hypothesis that NMDA receptors are involved in the control of PHN including allodynia and wind-up-like pain, and NMDA receptors also may play a role in the modulation of thermal perception. [1] Ketamine has the potential to become a primary effective treatment, which would simplify the therapeutic approach for PHN and may address the unmet need for more adequate and optimal treatment.

About Postherpetic Neuralgia

PHN is a complication of shingles. Shingles is caused by the reactivation of herpes zoster virus, which has remained dormant for decades in nerve ganglia after resolution of its primary infection (i.e. Chickenpox). [2, 3, 4] It is estimated that there are 1 million cases of herpes zoster annually in the U.S and about 15% to 20% of these cases develop PHN. [7,8]

PHN is defined as the persistent burning, sharp and jabbing pain or the deep and aching pain beginning ninety days after the onset of shingles rash and pain in the same location as the original rash. PHN may be intermittent or consistent and last days, weeks, months and even years. [2, 3, 4]

There is no single treatment that relieves PHN. It often takes a combination of treatments to reduce the pain and is typically based on the patient’s symptoms, age, circumstances, and other medical history. There are four classes of medications that are used to treat PHN: (a) topical local anesthetics, (b) tricyclic antidepressants with noradrenergic activity, (c) medications originally marketed as antiepileptic drugs, and (d) opioids (i.e. morphine, oxycodone and tramadol). [5, 6]

These treatments are often inadequate due to the localized activity of the topical options, and suboptimal dosing and long dose titration periods during which patients remain in unresolved pain in the systemic options. Thus, treatments often lead to non-compliance and/or switching to other medications, which are inadequate. Often the treatments become refractory. For these reasons, PHN results in a poor quality of life for these patients. [7] Secondary problems associated with PHN include inactivity, depression, and disuse of painful limbs. Non-pharmacological treatments for these secondary problems may include psychological counseling, physical therapy, exercise and acupuncture. [5, 6]

About Pharmather Inc.

Pharmather Inc., a wholly-owned subsidiary of Newscope Capital Corporation (CSE: PHRM), is a specialty life sciences

company focused on the research and development of psychedelic pharmaceuticals. Pharmather repurposes psychedelic pharmaceuticals, such as ketamine and psilocybin, for FDA approval to treat disorders of the brain and nervous system. Our team includes world-class strategic partners, advisors and a strong leadership team with a proven track record of success in drug development, business development and capital markets. Our goal is to advance the development of panaceAI™, our drug repurposing artificial intelligence platform, and our clinical product pipeline with ketamine and psilocybin in the treatment of Parkinson's Disease, depression, pain, traumatic brain injury and stroke. Learn more at: **pharmather.com** and follow us on **Facebook**, **Twitter** and **LinkedIn**.

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Cautionary Statement

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 Company's 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 Company will seek U.S. Food and Drug Administration ("FDA") approval under an Orphan Drug Designation ("ODD"), *leveraging existing scientific and clinical data to support the rapid advancement of our ketamine programs towards human clinical studies under the FDA regulatory pathway, 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**.*

References:

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