PharmaTher Signs Exclusive Worldwide License Agreement for Patented Ketamine Formulation Targeting Mental Health, Neurological and Pain Disorders

TORONTO, Jan. 19, 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, is pleased to announce that PharmaTher has entered into an Exclusive Worldwide License Agreement (the "Agreement") with the National Health Research Institutes ("NHRI") for the development and commercialization of a patented combination formulation of FDA-approved ketamine and betaine ("KETABET™") as a potential next-generation ketamine treatment for mental health, neurological and pain disorders.

KETABET™ has shown in clinical research to enhance the antidepressant effect while having the potential to significantly reduce the known negative side effects of ketamine.[1] Side effects such as hallucinations, confusion, memory loss and abuse liability compromise the compliance and potential therapeutic value of ketamine.

Through a proprietary microneedle ("MN") patch, KETABET™ aims to empower patients to dose their medication remotely, safely and conveniently rather than being under supervision by a healthcare provider at a certified medical office. KETABET™ MN patch has the potential to incorporate anti-tampering and anti-abuse features because of the combined presence of ketamine and betaine and the delivery format of the product that would parallel the approach used for the tamper-resistant transdermal fentanyl patch.

PharmaTher will seek FDA approval to conduct a Phase II clinical study for KETABET™ targeting the more than 300 million people who suffer from major depressive disorder and 100 million people who are resistant to available treatments worldwide.

"We believe KETABET™ has the potential to change the way mental health, neurological and pain disorders will be treated for the hundreds of millions of people globally who are suffering from these debilitating conditions," said Fabio Chianelli, CEO of PharmaTher. "We are pursuing the clinical development of KETABET™ to overcome the current limitations of ketamine and to unlock the known potential therapeutic value of ketamine for FDA approval."

Currently, pharmaceutical companies are developing new types of antidepressants. Approved antidepressants have significant limitations, including delayed response rates and unwanted side effects causing poor patient compliance and low remission rates.

Ketamine was approved by the FDA in 1970 and is clinically used for analgesia, sedation, and anesthetic induction.

Ketamine is emerging as a viable treatment option for depression. Recent clinical studies have shown that low dose ketamine produces a rapid-acting and sustained antidepressant effect in major depressive disorder[2], bipolar depression[3], depression with suicidal ideation[4] and post-traumatic stress disorder[5]. Despite this, the potential for abuse and misuse of ketamine and the adverse mental effects of ketamine use such as dissociative, hallucinogenic, and amnesic effects[6] leads to its limited clinical use and discontinuation.

The FDA granted Fast Track and Breakthrough Therapy designations for SPRAVATO® (esketamine) nasal spray. In March 2019, the FDA approved SPRAVATO®, in conjunction with an oral antidepressant, for treatment-resistant depression to Janssen Pharmaceuticals, Inc. According to the FDA, "because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under a Risk Evaluation and Mitigation Strategy."[7] The estimated annual cost per patient for SPRAVATO® could cost up to $49 thousand with limited reimbursement, whereas intravenous ketamine could cost up to $5,000 per patient annually without any reimbursement. Both require numerous administration sessions in a certified medical office under medical supervision by a health care provider.

COMPASS Pathways plc is developing COMP360 psilocybin therapy to be administered in conjunction with psychological support for treatment-resistant depression. In 2019, Compass Pathways plc completed a Phase I clinical trial and is currently evaluating COMP360 in a Phase IIb trial. The therapy protocol for COMP360, which would last approximately six to eight hours, includes the presence of a therapist and assisting therapist throughout the treatment session.[8]

PharmaTher aims to develop KETABET™ in a proprietary microneedle patch for FDA approval in certain mental health, neurological and pain disorders and provide the patient with a potentially convenient, safe and effective ketamine treatment through the combination of two FDA-approved drugs, ketamine and betaine.

Betaine anhydrous (CYSTADANE®) was approved by the FDA in 1996 for the treatment of homocystinuria to decrease elevated homocysteine blood concentrations.

There is growing evidence that betaine plays a critical role in regulating brain functions and has an antidepressant-like effect.[9] Betaine has been reported to prevent seizures in rodents[10], to improve symptoms of Rett syndrome[11], and to delay the onset

of neurologic impairment due to vitamin B12 deficiency[12] clinically. Furthermore, betaine attenuates memory deficits induced by homocysteine.[13]

Based on preclinical studies that supported the granted patent and patent applications of KETABET™, the combination of ketamine and betaine produced more robust antidepressant-like responses than their individual effects and that the combination blocked the psychotomimetic effects of ketamine.[1] This suggests that betaine can be considered as an add-on therapy to ketamine or as a fixed-dose combination therapy for treatment-resistant depression, treatment-resistant bipolar disorder, post-traumatic stress disorder, obsessive-compulsive disorder and chronic pain.

Under the terms of the Agreement, PharmaTher gained exclusive worldwide development and commercial rights to an intellectual property portfolio consisting of a granted patent (Taiwan patent: I648049) and patent applications (International Publication Number: WO2017205666A1) titled, "Method and composition for decreasing the psychotomimetic side effect and addictive disorder of ketamine" in the U.S., Europe, Japan, Canada, Israel and China.

Consistent with industry standards, PharmaTher paid a one-time fee for entering into the Agreement, and all other future payments will be based on clinical trial and revenue milestones reached by PharmaTher.

About The National Health Research Institutes

The National Health Research Institutes (NHRI) is a non-profit foundation established in 1995 by the government of Taiwan. Being an autonomous research organization under the supervision of the Department of Health, the NHRI is dedicated to the enhancement of medical research and the improvement of health care in this country. Scientists at the NHRI conduct mission-oriented medical research and investigate many aspects of the basic biomedical sciences, as well as specific diseases. These range from the common problems such as aging, cancer, infectious diseases, mental disorders, occupational diseases, to health policy. For more information about the NHRI visit www.nhri.edu.tw.

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 and psilocybin, for FDA approval to treat mental health, neurological and pain disorders.

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

For more information, please contact:

Fabio Chianelli
Chief Executive Officer
PharmaTher Inc.
Tel: 1-888-846-3171
Email: **info@pharmather.com**
Website: **www.pharmather.com**

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

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 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 development and commercialization of a patented combination formulation of FDA-approved ketamine and betaine ("KETABET™") as a potential next-generation ketamine treatment for mental health, neurological and pain disorders, KETABET™ aims to empower patients to dose their medication remotely, safely and conveniently rather than being under supervision by a healthcare provider at a certified medical office, KETABET™ MN patch has the potential to incorporate anti-tampering and anti-abuse features, seek FDA approval to conduct a Phase II clinical study, intellectual property portfolio, psychedelic pharmaceuticals, 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. J.-C. Lin, M.-Y. Lee, M.-H. Chan, Y.-C. Chen, H.-H. Chen, Betaine enhances antidepressant-like, but blocks psychotomimetic effects of ketamine in mice, Psychopharmacology (Berl). 233 (2016) 3223–32
2. Murrough et al. 2013; Wan et al. 2014
3. Ionescu et al. 2015; Nugent et al. 2014; Rybakowski et al. 2013
4. Aligeti et al. 2014; Thakurta et al. 2012; Zigman and Blier 2013
5. Feder et al. 2020
6. Krystal et al. 1994; Perry et al. 2007
7. https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified
8. Compass Pathways pls F-1 Filing dated 2020-08-28
9. Freed 1984; 1985
10. Kim et al. 2013; Di Pierro et al. 2015
11. Percy and Lane 2005
12. van der Westhuyzen and Metz 1984
13. Chai et al. 2013