Press Releases

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PharmaTher Announces FDA Approval of Investigational New Drug (IND) Application for Ketamine to Treat ALS

TORONTO, January 12, 2022 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a company focused on the development and commercialization of specialty ketamine prescription-based products, today announced that the U.S. Food and Drug Administration (“FDA”) has accepted an investigator-initiated investigational new drug ("IND") application to proceed with a Phase 2 clinical trial (the “Study”) evaluating ketamine in the treatment of Amyotrophic Lateral Sclerosis (“ALS”), also known as Lou Gehrig's disease. The Study will be conducted at the University of Missouri led by the Study’s Primary Investigator, Dr. Richard Barohn, M.D.

The IND follows the FDA granting orphan drug designation for ketamine in treating ALS to PharmaTher and on December 23, 2021, President Biden signing into law H.R. 3537, the “Accelerating Access to Critical Therapies for ALS Act,” which requires the Department of Health and Human Services to create grant programs, a public-private partnership, and an action plan for the study of amyotrophic lateral sclerosis and other neurodegenerative diseases, including investigational drugs.

Assuming the Study is positive, the Company will request a meeting with the FDA to discuss its plan and obtain an agreement to move to a Phase 3 clinical study and accelerated marketing approval.

The Phase 2 clinical trial is a prospective, double-blind, randomized

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in each cohort. The primary endpoint is the proportion of participants at each ketamine dose with dose limiting toxicities at 12 weeks and 24 weeks. Secondary endpoints include changes from baseline in participant plasma neurofilament-light chain; change in slope of the ALS Functional Rating Scale–Revised (ALSFRS-R); changes from baseline in percentage of subjects with depression as measured by the PHQ-9; change in slope of manual muscle strength testing; and change in slope of forced vital capacity.

Fabio Chianelli, Chief Executive Officer of PharmaTher, said, "We are very pleased to have supported Dr. Barohn and his team by providing information for the IND that achieved FDA acceptance to conduct the Phase 2 clinical study. ALS is a devastating neurodegenerative disease with limited treatment options and ketamine, based on preclinical research, has the potential to have a positive impact on ALS patients."

Dr. Barohn, the Study's Primary Investigator who received the IND acceptance letter from the FDA, is Executive Director, NextGen Precision Health and Executive Vice Chancellor for Health Affairs, MU Health Care at the University of Missouri. Dr. Barohn, a neurologist, is an internationally known neuromuscular disorders clinician and researcher. His research specializes in rare neuromuscular disorders such as forms of muscular dystrophy and ALS. In 2018, he was elected to the Association of American Physicians. Throughout his career, he has attained funding of more than $80 million from federal organizations and other resources to advance clinical and translational science. He is an author in more than 400 peer-reviewed publications and he is an author in one of the standard neurology textbooks, DeJong's The Neurologic Examination.

About Ketamine for ALS

ALS is a devastating neurodegenerative disease characterized by muscle weakness that rapidly progresses to paralysis due to motor neuron loss in the brain and spinal cord. Currently, there is no known cure for ALS and life expectancy is two to six years after diagnosis. ALS affects approximately 50,000 people in the U.S. and Europe, with over 5,000 new cases diagnosed annually. The FDA approved only three pharmaceuticals for the treatment of ALS: riluzole, edaravone, and Nuedexta. These drugs are effective against disease mechanisms of ALS, but fail to have measurable effects on attenuating disease progression or improve survival.

Ketamine may indirectly attenuate NMDA receptor-related glutamate excitotoxicity. A study in the SOD1-G93A mouse model of ALS showed that the administration of ketamine had neuroprotective effects, preserves muscle function in advancing ALS and increases life expectancy when given in the early stages of muscle decline. Thus, ketamine, when used for ALS, may slow disease progression, alleviate symptoms, and/or prolong survival to positively impact the lives of patients with ALS and their family members.

PharmaTher has an exclusive license agreement with The University of Kansas ("KU") for the development and commercialization of the intellectual property of ketamine in the treatment of ALS.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is focused on the development and commercialization of specialty ketamine prescription-based products such as KETAPATCH™, a ketamine microneedle patch for mental health and pain disorders, and KETARX™, a ketamine hydrochloride injection USP product for anesthesia, procedural sedation and neurological disorders including Parkinson's disease and Amyotrophic Lateral Sclerosis.

Learn more at **PharmaTher.com**, **Twitter** and **LinkedIn**.

For more information about PharmaTher, please contact:

Fabio Chianelli
Chief Executive Officer
PharmaTher Holdings Ltd.
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.

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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", "aim", "may" and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on PharmaTher Holdings Ltd. (the "Company") current belief or assumptions as to the outcome and timing of such future events. 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 31, 2021 ("MD&A"), dated October 27, 2021, 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

Comments are closed.

Publicly-traded on the OTCQB: **PHRRF** and CSE: **PHRM**