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

TORONTO, Jan. 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 controlled multiple ascending dose study of ketamine, which will enroll a total of 36 participants with ALS in 3 sequential cohorts, with 12 participants 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.

About PharmaTher Holdings Ltd.

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**.

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