PharmaTher Provides Research and Development Update and Milestones for 2021

TORONTO, June 10, 2021 (GLOBE NEWSWIRE) -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a clinical-stage psychedelics biotech company, is pleased to provide an update on the research and development initiatives of its psychedelic product programs and upcoming milestones for 2021.

“We are well-positioned, both financially and operationally, to execute on our remaining milestones for 2021, which includes completing a Phase 2 study with ketamine to treat Parkinson’s disease, a Phase 2 study with KETABET™ for treatment-resistant depression, and the development of our novel microneedle patches for delivering psychedelics such as ketamine, psilocybin, DMT, MDMA and LSD,” said Fabio Chianelli, CEO of PharmaTher. “The recent FDA acceptance of our IND to proceed to a Phase 2 study in Parkinson’s disease will pave the way for us to confidently submit future IND’s and advance clinical studies evaluating novel uses, formulations and delivery forms of psychedelics to treat various mental health, neurological and pain disorders.”

FDA Phase 2 Clinical Studies

For the rest of 2021, PharmaTher will focus on advancing three promising developments through clinical studies:

Ketamine for Parkinson’s Disease

Following the FDA acceptance of the Company’s investigational new drug application to proceed with a Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of ketamine in the treatment of levodopa-induced dyskinesia in patients with Parkinson’s disease, the Company has begun clinical trial start-up activities to begin enrolling patients in Q3-2021 and to announce clinical results in Q4-2021.

For those interested in the study (*ClinicalTrials.gov Identifier: NCT04912115*), titled “A Multi-Center, Phase II, Randomized, Double-Blind, Prospective, Active Placebo-Controlled Trial of Sub-Anesthetic Intravenous Infusion of Ketamine to Treat Levodopa-Induced Dyskinesia in Subjects with Parkinson's Disease,” please visit https://clinicaltrials.gov/ct2/show/NCT04912115?term=PharmaTher&draw=2&rank=1.

Assuming the Phase 2 clinical trial 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 under the 505(b)2 regulatory pathway in 2022.

KETABET™ for Treatment-Resistant Depression

The Company is preparing a pre-IND meeting request and briefing documents to submit to the FDA to support the clinical development of KETABET™ and the Phase 2 study for treatment-resistant depression. The Company intends to file the pre-IND meeting request this month, obtain FDA feedback on its clinical study design, and file the IND in Q3-2021.

With the overlap of the clinical operations from the Parkinson’s disease study, the Company has already activated start-up activities and identified potential clinical sites to screen and enroll patients for the proposed Phase 2 study in Q3/Q4-2021. The aim is to share clinical results by the end of this year.

Amyotrophic Lateral Sclerosis (“ALS” or “Lou Gehrig’s Disease”)

Following the Company’s recent submission to receive orphan drug designation for ketamine to treat ALS, the Company is working with its clinical advisors in finalizing a proposed Phase 2 study design. The objective is to request a pre-IND meeting with the FDA in Q3-2021 and submit the IND in Q4-2021.

PharmaTher has an exclusive license agreement with the University of Kansas for the intellectual property protecting the potential use of ketamine to treat ALS, which was discovered by Dr. Richard J. Barohn, M.D., John A. Stanford, Ph.D., and Dr. Matthew Macaluso, D.O. Preclinical research has shown that the administration of ketamine preserves muscle function in advancing ALS and increases life expectancy when given in the early stages of muscle decline.

Microneedle Patch for the Delivery of Psychedelics

For the second half of 2021, PharmaTher will focus on working with its research and development partners to advance next generation microneedle patches for the delivery of psychedelics:

Hydrogel-Forming Microneedle Delivery System for Ketamine

PharmaTher is working with Professor Ryan Donnelly under a research agreement with The Queen’s University of Belfast to finalize the patented hydrogel-forming microneedle patch development to deliver ketamine and KETABET™.

The research leverages the successful proof of concept achieved in delivering esketamine, the S(+) enantiomer of ketamine,

via the microneedle patch, which may overcome the drawbacks associated with ketamine administration in an intravenous or nasal spray format. Details of the research can be found in a published paper titled "Hydrogel-forming microneedle arrays as a therapeutic option for transdermal esketamine delivery."

Validation and tech transfer to support clinical studies will be completed in Q4-2021. Interim development results will be made available as they arise throughout 2021.

Microdosing Psychedelics with GelMA Microneedle Delivery System

The Company is working with the Terasaki Institute, led by Dr. Ali Khademhosseini, under a research agreement to finalize the development of a proprietary microneedle delivery system comprised of a biocompatible and biodegradable gelatin methacryloy ("GelMA") composite for use with psychedelics such as psilocybin, DMT, MDMA and LSD.

The GelMA patch delivery system is the driving force of the Company's psychedelics microdosing program. It is expected that validation results in delivering these psychedelics will be completed in Q4-2021. Interim development results will be made available as they arise throughout 2021.

Clinical Manufacturing and Supply

The Company entered into a Co-Development Agreement with TSRL, Inc. to jointly develop a patented hydrogel-forming microneedle patch delivery technology licensed from The Queens University of Belfast, to control the manufacturing and supply of microneedle patches for the Companies respective clinical and commercial drug programs.

PharmaTher is focused on incorporating psychedelics (i.e. ketamine, psilocybin, DMT, MDMA and LSD) and TSRL is focused on incorporating antiviral medications (i.e. Zanamivir, other antiviral therapeutics and vaccines) in a microneedle patch with the potential to improve the safety (i.e. fewer side effects), efficacy (i.e. bioavailability, optimized dosing regimen including continuous system delivery) and compliance (i.e. storage, distribution and self-administration) of these compounds that currently must be taken orally, inhaled, injected and intravenously.

Recent activities included the tech transfer for scale-up and manufacturing of clinical supplies to a GMP contract research lab and a pre-IND meeting with the FDA that achieved agreement with the agency on proposed 505(b)2 product development plans.

The Company aims to validate clinical production of the microneedle patch this year and to enter into clinical studies in 2022 to deliver certain psychedelics such as ketamine, psilocybin, DMT, MDMA and LSD.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is a clinical-stage psychedelics biotech company focused on the research, development and commercialization of novel uses, formulations and delivery methods of psychedelics to treat mental health, neurological and pain disorders. PharmaTher is currently conducting an FDA approved phase 2 clinical study with ketamine to treat Parkinson's disease and is developing a novel microneedle patch for the intradermal delivery of psychedelics.

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

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*discussion and analysis for the period of February 28, 2021 ("MD&A"), dated April 28, 2021, which is available on the Company's profile at **www.sedar.com**.*

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