PharmaTher Granted FDA Orphan Drug Designation For Ketamine To Treat Complex Regional Pain Syndrome

- *Achieving its second FDA orphan drug designation with ketamine.*
- *Building a proprietary ketamine-based product pipeline for rare and near-rare disorders in pain and inflammation.*
- *Seeking to enter Phase 2 clinical trial in 2022.*

TORONTO, Oct. 13, 2021 (GLOBE NEWSWIRE) -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a clinical-stage psychedelics biotech company, is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) for ketamine in the treatment of complex regional pain syndrome (CRPS), a rare chronic pain and inflammatory condition following an injury to a limb (arm, leg, hand or foot). This follows the FDA ODD grant of ketamine for the treatment of Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease, announced by the Company on August 4, 2021.

Fabio Chianelli, Chief Executive Officer of PharmaTher, said, “Receiving our second FDA orphan drug designation with ketamine for CRPS continues our momentum in building a specialty ketamine-based product pipeline for not only mental health disorders, but also for rare and near-rare conditions present in neurological (Parkinson’s disease, ALS), pain and inflammatory disorders. We expect to pursue a Phase 2 clinical study using our proprietary cGMP ketamine product in 2022 for CRPS.”

CRPS is a debilitating condition characterized by severe, continuous, burning or throbbing pain in a limb. CRPS is known as one of the most painful disorders and the risk of suicide is significantly higher in patients with CRPS with one study demonstrating that 75% of patients had a high risk for suicide (Lee et al., Psychiatry Investig 2014;11(1):32-8). CRPS has acute (recent, short-term) and chronic (lasting greater than six months) forms of excessive pain accompanied by changes in skin color, temperature and/or swelling, which results in loss of physical function and can lead to significant and sometimes permanent disability. CRPS can occur after surgery or trauma, including brain or spinal cord injury. There is currently no medication approved for the treatment of CRPS.

Ketamine acts as a noncompetitive, NMDA channel blocker that can prevent the induction of synaptic potentiation. NMDA receptors play a central role in the processes of induction and maintenance of pain sensitization, accounting for the analgesic efficacy of ketamine. Although ketamine has actions at other relevant sites, including nicotinic and opioid receptors, as well as, via monoamine reuptake transporters, it is likely that both the anesthetic and the analgesic actions of ketamine are largely mediated by NMDA receptor antagonism. Likewise, the psychotropic and sympatho-excitatory side effects of ketamine are also predominantly mediated through NMDA receptor blockade.

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 orphan 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. Orphan drug designation would qualify a drug 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 clinical drug testing costs, activities, eligibility for orphan drug grants, and the waiver of the FDA New Drug Application filing fee of approximately $2.4 million.

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, such as ketamine, to treat mental health, neurological and pain disorders. PharmaTher is currently initiating 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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