PharmaTher Holdings Provides Update for KETARX™ (Racemic Ketamine) Development Programs and Expected Milestones for 2023

Company aims to commercialize wholly-owned KETARX™ (racemic ketamine) for mental health, neurological and pain disorders

Company aims to seek FDA approvals for KETARX™ via the ANDA and 505(b)(2) regulatory pathways in H2-2023

Company aims to advance clinical development programs of KETARX™, including (i) Phase 3 clinical study for Parkinson's disease; (ii) Phase 2 clinical study with microneedle patch; and (iii) Phase 2 clinical study for Amyotrophic lateral sclerosis

Company granted 4 FDA orphan drug designations

TORONTO, Jan. 11, 2023 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a leader in specialty ketamine pharmaceuticals, today provided an update for its clinical development programs and milestones for 2023 with KETARX™ (racemic ketamine) as a potential treatment for mental health, neurological and pain disorders.

Fabio Chianelli, CEO of PharmaTher, commented: "We have made key development progress in 2022 that paves the way for potential near-term commercialization opportunities with our own racemic ketamine, which we brand as KETARX™, for multiple indications in mental health, neurological and pain disorders. In 2023, we are focused on seeking one or more FDA approvals for KETARX™ via the ANDA and 505(b)(2) regulatory pathways, advancing late-stage clinical studies, and attracting strategic partnerships that will unlock the value of our product pipeline and drug delivery technologies."

PharmaTher's Focus on Racemic Ketamine

Racemic ketamine was approved by the U.S. Food and Drug Administration ("FDA") in 1970 and is clinically used for analgesia, sedation, and anesthetic induction. Racemic ketamine is an equal mixture of two isoforms known as R and S ketamine. The two isomers bind differently in the body and brain, resulting in differences in pharmacology and metabolism. Of the three forms of ketamine, only racemic ketamine and S-ketamine products have been approved by FDA. Racemic ketamine has the longest history of medical use. The medical community's understanding of the potential impact of ketamine on human health is the result of clinical research and off-label use of racemic ketamine for indications such as, depression, suicidal ideation, substance abuse, post-traumatic stress disorder, and various pain and neurological disorders. Recently, evaluation of the isolated enantiomers relative to different disorders has led to the approval of S-ketamine (i.e. SPRAVATO®); however, the approval of new pharmaceuticals with either of the isolated enantiomers (i.e. R-ketamine) is still in the distant future.

The Company believes it is in a unique position to unlock the commercial and therapeutic potential of KETARX™ (racemic ketamine) in the near term by leveraging its indication-specific patents, FDA orphan drug designations, and drug delivery technologies (i.e. microneedle patch and on-body pump devices). The aim is to obtain FDA approvals through the less burdensome abbreviated new drug application ("ANDA") and 505(b)(2) regulatory pathways as compared to new chemical entity clinical development.

KETARX™ Development Program Updates and Anticipated Milestones:

1. *KETARX™ for FDA approval via the ANDA regulatory pathway in H2-2023*

PharmaTher aims to commercialize KETARX™, a non-barbiturate anesthetic used for the induction and maintenance of general anesthesia for diagnostic and surgical procedures. Available dosage forms will include 10 mg/1ml, 50 mg/ml and 100 mg/ml, with the option to increase concentration and ready-to-administer applications. The Company seeks to file an ANDA with the FDA by Q2-2023 and expects to obtain FDA approval in 2023. The Company forecasts that it could sell up to one million units at an average wholesale price between USD $25 and USD $40 per unit, resulting in potential total gross sales of USD $25-40 million.

2. *KETARX™ for FDA approval to treat Complex Regional Pain Syndrome via the 505(b)(2) regulatory pathway in H2-2023*

PharmaTher received an FDA orphan drug designation for ketamine in treating complex regional pain syndrome ("CRPS"), a rare chronic pain and inflammatory condition. The Company recently received FDA guidance via a Type C meeting on KETARX™'s requirements prior to submitting a new drug application ("NDA") for approval in CRPS. PharmaTher believes that there is a pathway to submit an NDA with available non-clinical and clinical data, and its own chemistry, manufacturing, and controls ("CMC") information by the end of 2023. The Company is currently preparing its final plans, which include a robust pharmacokinetic study to potentially satisfy FDA's requirements for an NDA submission.

3. *KETARX™ On-body Pump for FDA approval via the 505(b)(2) regulatory pathway in H2-2023*

PharmaTher aims to commercialize KETARX™ On-body Pump (subcutaneous racemic ketamine) for the maintenance of general anesthesia for diagnostic and surgical procedures. The Company believes that subcutaneous infusion of racemic ketamine via the on-body pump device has several advantages for ketamine procedural sedation, including decreased

requirement for skilled personnel for its administration, reduction in pain and irritation associated with administration, and a reduced risk of systemic infection and other complications seen with IV administration. The FDA is expected to grant a Type C meeting to provide feedback on the requirements to file an NDA via the 505(b)(2) regulatory pathway. PharmaTher believes there is a pathway to submit an NDA with available non-clinical and clinical data, and its own CMC information by the end of 2023.

4. *KETARX™ Microneedle Patch via the 505(b)(2) regulatory pathway in H2-2023*

The Company recently completed the development of the microneedle patch system for the intradermal delivery of sustained low-dose ketamine. This milestone has enabled progression toward process validation and the manufacturing of cGMP clinical materials to support ongoing clinical development. PharmaTher aims to submit a pre-IND meeting with the FDA to agree on the proposed overall clinical development program via the 505(b)(2) regulatory pathway and expects to initiate a Phase 2 study in H2-2023.

5. *KETARX™ Type C meeting granted by FDA for potential Phase 3 clinical study in the treatment of levodopa-induced dyskinesia in Parkinson's disease patients*

PharmaTher recently announced the presentation of the Phase 1/2 clinical study involving ketamine in the treatment of levodopa-induced dyskinesia in Parkinson's disease ("LID-PD"). The data from this study demonstrated ketamine's safety and tolerability with clinically meaningful efficacy that supports further investigation in a proposed Phase 3 clinical study as a potential new treatment for LID-PD. Accordingly, the Company was granted a Type C meeting with the FDA to discuss its proposed Phase 3 clinical study, which would pave the way for FDA approval under the 505(b)(2) regulatory pathway. PharmaTher retains rights to US Patent No: 11,426,366 (expires May 2036), titled "Compositions and Methods for Treating Motor Disorders," which includes claims intended to cover ketamine in the potential treatment of Parkinson's Disease and motor disorders that cause involuntary or uncontrollable movement or actions of the body.

6. *KETARX™ in Phase 2 clinical study in the treatment of ALS*

PharmaTher received an FDA orphan drug designation for ketamine in the treatment of amyotrophic lateral sclerosis ("ALS"), a progressive neuromuscular disease with a life expectancy of two to six years after diagnosis. The Company announced that the FDA had accepted an investigator-initiated IND to proceed with a Phase 2 clinical study evaluating ketamine for ALS. The study's primary investigator is Dr. Richard Barohn, M.D. Currently, the Company is evaluating potential grant funding to support the initiation of the study. Upon completion of the study, PharmaTher aims to seek guidance from the FDA to determine the final clinical development plan.

7. *KETARX™ FDA orphan drug designations*

The Company currently holds four orphan drug designations granted by the FDA for KETARX™ (racemic ketamine), which include:

- Prevention of Ischemia-reperfusion injury from organ transplantation;
- Treatment of Status Epilepticus;
- Treatment of Amyotrophic Lateral Sclerosis; and
- Treatment of Complex Regional Pain Syndrome.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is a specialty pharmaceutical company focused on developing and commercializing KETARX™ (racemic ketamine) delivered by intravenous injection, microneedle patch, and on-body pump to treat mental health, neurological and pain disorders. Learn more at **PharmaTher.com.**

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