



PharmaTher Holdings Provides Corporate Update

Company funded to meet upcoming milestones over the next 24 months

Expected FDA approval for KETARX™ (racemic ketamine) via the ANDA pathway in Q1-2024 and international approvals after that

Company advancing PharmaPatch™ (microneedle patch) for psychedelics and infectious diseases

Streamlined clinical development programs to focus on near-term investment and revenue opportunities with KETARX™ and PharmaPatch™

TORONTO, June 12, 2023 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a commercial-focused specialty pharmaceutical company, provides a corporate update outlining the development and commercialization plans and upcoming milestones for its KETARX™ (racemic ketamine) products and PharmaPatch™ (microneedle patch) delivery system. With approximately CAD \$6 million in cash as of end-May 2023, the Company is funded to meet its upcoming milestones targeting near-term investment and revenue opportunities over the next 24 months.

Fabio Chianelli, CEO of PharmaTher, commented: “Since our inception, we focused on developing novel uses and delivery forms of ketamine for mental health, neurological and pain disorders. We dedicated our resources to working with the FDA to obtain agreement on our regulatory and clinical development plans for our ketamine-based product pipeline. In parallel, we developed our own racemic ketamine product, KETARX™, to meet the growing demand for ketamine in the U.S. and international markets. Currently, ketamine is on the FDA drug shortages list, and we aim to recover ketamine’s shortage issue in the U.S. and become a global leader for ketamine-finished products. We expect to receive FDA approval for KETARX™ in Q1-2024. Also, we are adding a new investment and revenue stream by partnering our proprietary microneedle patch delivery system, PharmaPatch™, with biotech and pharmaceutical companies globally. As for our proposed clinical development programs involving ketamine, we are pausing capital allocations to these programs for 2023 to focus on entering the next phase of our growth cycle in becoming a commercial-focused specialty pharmaceutical company.”

KETARX™ (racemic ketamine)



PharmaTher's priority is to commercialize KETARX™ under [ketamine's FDA-approved label](#). The Company expects to market various dosage forms of KETARX™, such as 10 mg/ml, 50 mg/ml and 100 mg/ml, with the option to increase concentration and ready-to-administer applications for the U.S. and international markets. Ketamine is currently on the [FDA's drug shortage list](#). Outside of the FDA approved indications, ketamine is also being administered in hospitals and clinics to treat various disorders encompassing mental health, neurological and pain.

The Company expects to file its abbreviated new drug application ("ANDA") with the FDA in early July and obtain FDA approval in Q1-2024. Also, the Company will pursue international approvals for KETARX™ to support the growing global demand for ketamine. The Company is in discussion with a specialty pharmaceutical company to market, distribute and sell KETARX™ in the U.S.

PharmaPatch™ (microneedle patch)

PharmaPatch™ is a proprietary microneedle-enhanced delivery system offering an efficient and painless method for delivering drugs, including psychedelics and medicines to treat infectious diseases. PharmaPatch™ may enable flexible drug load capacity and combinations, controlled released delivery, and the ability to present desired pharmacokinetic and safety profiles. In addition, PharmaPatch™ aims to empower patients to dose their medication remotely, safely and conveniently rather than under the supervision of a healthcare provider at a clinic or hospital due to its potential anti-tampering and anti-abuse features.

The Company has completed research studies demonstrating that PharmaPatch™ can deliver ketamine, psilocybin, MDMA, DMT and LSD and is now initiating final product, clinical and regulatory plans for a potential clinical study with the KETARX™ (ketamine) patch in 2024.

In addition, the Company is expanding its commercialization efforts with PharmaPatch™ in providing research, development and manufacturing services to potential pharmaceutical partners. PharmaPatch™ offers potential partners a differentiated and validated delivery system, desired pharmacokinetic profiles, intellectual property protection, and cGMP materials for IND-enabling and clinical studies to support regulatory approvals. The Company is actively engaged in partnering discussions for the use of PharmaPatch™ to deliver psychedelics and potential infectious disease treatments in addition to the various collaborations already in place with



several pharmaceutical companies. Such partnerships may offer an additional investment and revenue stream through equity, licensing, milestones, royalties and development fees.

Clinical Programs Update

Following numerous interactions with the FDA regarding clinical programs involving ketamine, the various development and clinical studies requirements to advance them towards FDA approval, and with the current market environment, the Company will focus resources on potential near-term investment and revenue opportunities that exist and that are synergistic with KETARX™ and PharmaPatch™. As such, the Company has decided to pause allocating funds for its product and clinical programs, including its on-body pump system, Parkinson's disease, Amyotrophic Lateral Sclerosis, Rett Syndrome, and Complex Regional Pain Syndrome for the remainder of 2023. The Company will evaluate these programs quarterly to determine a potential rationale to reviving one or more of them internally or with potential pharmaceutical partners.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) develops and commercializes specialty pharmaceuticals exhibiting growing adoption and permitting novel delivery methods to enhance patient outcomes. The Company's lead product is KETARX™ (racemic ketamine) to fill the global unmet medical needs for anesthesia, sedation, pain, mental health, and neurological indications. The Company is commercializing PharmaPatch™ (microneedle patch) with its partners to deliver psychedelics and drugs to treat infectious diseases. Learn more at PharmaTher.com.

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