PharmaTher Provides Update of its Priority Original Abbreviated New Drug Application for Ketamine

TORONTO, April 18, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, today announced receipt of a Complete Response Letter (“CRL”) for its Priority Original Abbreviated New Drug Application (“ANDA”) for Ketamine that was accepted by the U.S. Food and Drug Administration (the “FDA”) and assigned a Generic Drug User Fee Amendments of 2022 (“GDUFA”) goal date of April 29, 2024. The CRL is similar to the review letter FDA provided on possible deficiencies identified by Quality, as announced on February 12, 2024, and no additional deficiencies were mentioned in the CRL. As such, the Company has completed the necessary tests and responses to address the FDA’s comments and will submit them to the FDA for their review and response to a new GDUFA goal date. The Company will provide updates as they occur.

Fabio Chianelli, CEO of PharmaTher, commented: “Although we will not receive approval on the GDUFA goal date of April 29, 2024, we are pleased that the FDA review of our ANDA has been completed and no additional deficiencies were mentioned from its original review letter. We have completed the necessary tests and are confirming to ensure our responses accurately reflect the FDA’s comments. We will submit them to address the CRL and obtain a revised GDUFA goal date. I believe that our goal to receive FDA approval for ketamine is closer.”

The Company’s overall goal is to solve the ketamine shortage problem in the U.S. and its ketamine to adhere to the FDA’s strict manufacturing guidelines and FDA-approved prescribing label. Following the anticipated FDA approval and launch in the U.S., the Company aims to pursue international approvals to support the global demand for ketamine. The Company’s long-term strategy is pursuing novel uses and delivery methods of ketamine as a potential treatment for pain, mental health, and neurological disorders.

Ketamine has been on the FDA’s drug shortage list since February 2018, which is believed to have encouraged the widespread availability of compounded ketamine products not FDA approved for psychiatric disorders. On October 10, 2023, the FDA published a compounding risk alert describing the potential risks associated with compounded ketamine products for psychiatric disorders, specifically from telehealth providers that provide in-home ketamine services. These compounded ketamine products are not FDA approved.

Ketamine is an essential medicine used for anesthesia and analgesia (pain relief) listed on the WHO Essential Medicines List. In Canada, ketamine has been classified as a Tier 3 drug shortage since February 2023, and Health Canada has approved ketamine for use as a sedative and painkiller in hospital settings. Outside of the FDA and Health Canada approved indications, ketamine is also being administered in hospitals and clinics to treat various mental health, neurological and pain disorders. A recently published new peer-reviewed study on the real-world effectiveness of ketamine intravenous therapy demonstrated significant patient improvement for depression, anxiety and suicidal ideation.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is focused on the development and commercialization of KETARX™ (Ketamine) to fill the global unmet medical needs for anesthesia, sedation, pain, mental health, and neurological indications. PharmaTher owns 49% of Sairiyo Therapeutics Inc., which focuses on advancing the clinical development of an improved and patented enteric-coated orally bioavailable formulation of cepharanthine (PD-001) to treat responsive cancers and infectious diseases, including COVID-19. Learn more at **PharmaTher.com.**

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assumptions that have been made by the Company at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information. Given these risks, uncertainties and assumptions, you should not unduly rely on these forward-looking statements. The forward-looking information contained in this press release is made as of the date hereof, and Company is not obligated to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable securities laws. The foregoing statements expressly qualify any forward-looking information contained herein. Factors that could cause actual results to differ materially from those anticipated in these forward-looking statements are described under the caption "Risk Factors" in Company's management's discussion and analysis for the three and six months ended November 30, 2023 ("MD&A"), dated January 26, 2024, which is available on the Company's profile at www.sedarplus.ca.

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