PharmaTher Announces Update on FDA New Drug Application for Ketamine

TORONTO, Sept. 04, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, today announced an update for its New Drug Application for Ketamine from the U.S. Food and Drug Administration (the “FDA”) with an assigned a Generic Drug User Fee Amendments of 2022 (“GDUFA”) goal date of October 29, 2024. On September 3, 2024, the FDA communicated with the Company that the review is ongoing and no additional information is needed, but is subject to change. The Company will continue to provide updates as they occur.

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 and its commercial development strategy to treat Parkinson’s Disease. In addition, the Company will pursue novel uses and delivery methods of ketamine for mental health, pain, neurological and medical countermeasures indications.

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. 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, neurological, and medical countermeasures 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) for viral infectious diseases and medical countermeasures. Learn more at **PharmaTher.com**.

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Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.

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This press release contains 'forward-looking information' within the meaning of applicable Canadian securities legislation. These statements relate to future events or future performance. The use of any of the words “closer”, "could", “confident”, "would", "intend", "expect", "believe", "will", "projected", "estimated", "potential", "aim", “may”, “plan”, “proposed”, “lead”, “toward”, “anticipate”, and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on PharmaTher Holdings Ltd. (the "Company") current belief or assumptions as to the outcome and timing of such future events. Forward-looking information is based on reasonable 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 nine months ended February 29, 2024 ("MD&A"), dated April 19, 2024, which is available on the Company's profile at www.sedarplus.ca.

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