PharmaTher Announces Post Complete Response Letter Clarification Meeting Request Granted from the FDA for Ketamine Abbreviated New Drug Application

TORONTO, November 13, 2024 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, today announced that the Company requested a post-complete letter clarification meeting (the "Meeting") in response to the FDA issuing a complete response letter (CRL), dated October 22, 2024, for the ketamine Abbreviated New Drug Application, which was assigned a Generic Drug User Fee Amendments of 2022 ("GDUFA") goal date of October 29, 2024.

On November 12, 2024, the FDA granted the Meeting scheduled for November 29, 2024. Due to the U.S. Thanksgiving Holiday and scheduling conflicts of attendees from its CDMO partner, the Company has requested to reschedule the Meeting for the following week. The Company requested the Meeting to ensure responses to the CRL align with the FDA's requests, leaving nothing to chance. The Company will announce the new Meeting date once it becomes available, propose a timeline for the resubmission to this CRL, and continue to provide updates as they occur.

As announced on October 23, 2024, the deficiencies cited in the CRL are classified as MINOR, and the resubmission to this CRL will be considered a MINOR AMENDMENT. The FDA requested new and updated information and clarifications related to drug substance, drug product, manufacturing, and microbiology. The FDA did not express concern about the stability of the ketamine submission batches, which achieved 18 months of stability without issue, and no new preclinical and clinical studies were requested.

The Company is committed to its overall goal to solve the ketamine shortage problem in the U.S. and 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. 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.

Cautionary Statement

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 year ended May 31, 2024 originally filed on September 26, 2024, has been refiled to correct the date of the MD&A from "September 23, 2024" to "September 26, 2024", which is available on the Company's profile at www.sedarplus.ca.

This news release does not constitute an offer to sell or the solicitation of an offer to buy, and shall not constitute an offer, solicitation or sale in any state, province, territory or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state, province, territory or jurisdiction.