



PharmaTher Announces Assigned FDA Approval Goal Date of its Priority Original Abbreviated New Drug Application for Ketamine

The FDA Assigned Goal Date is October 29, 2024

TORONTO, May 10, 2024 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, today announced receipt of an Amendment Acknowledgment Letter ("AAL") for its Priority Original Abbreviated New Drug Application ("ANDA") for Ketamine from the U.S. Food and Drug Administration (the "FDA") and assigned a Generic Drug User Fee Amendments of 2022 ("GDUFA") goal date of October 29, 2024. As announced by the Company on April 18, 2024, the receipt of a Complete Response Letter ("CRL"), similar to the review letter FDA provided on possible deficiencies identified by Quality, as announced on February 12, 2024. There were no additional deficiencies mentioned in the CRL and AAL. The Company, demonstrating its commitment to quality and compliance, promptly completed the necessary tests and responses to address the FDA's comments and submitted them to the FDA for their review, which resulted in the GDUFA goal date of October 29, 2024. The Company will provide updates as they occur.

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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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 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.

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.