PharmaTher Provides Complete Response Amendment for US FDA New Drug Application for Ketamine

Expecting FDA approval of Ketamine in Q2-2025

Solving the shortage problem of Ketamine and unlocking its pharmaceutical potential

Toronto, Ontario--(Newsfile Corp. - March 3, 2025) - PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) (the "Company" or "PharmaTher"), a specialty pharmaceutical company, is pleased to announce today that the Company has provided its resubmission to the complete response amendment for its U.S. Food and Drug Administration ("FDA") new drug application for Ketamine, which addresses the deficiencies classified as MINOR in the complete response letter ("CRL") provided by the FDA dated October 22, 2024.

Fabio Chianelli, Chairman and CEO of PharmaTher, commented: "I am very pleased that we have addressed all the minor deficiencies detailed in the FDA complete response letter and completed the resubmission response to support our FDA new drug application for Ketamine. This submission is a significant step towards obtaining FDA approval. I look forward to sharing our revised FDA approval goal date, which is expected to be in Q2-2025, with our shareholders and the medical community."

Expecting FDA approval of Ketamine in Q2-2025

PharmaTher has addressed the deficiencies in the CRL and expects to receive a new approval date for a Q2-2025 FDA approval. As noted by the FDA in the CRL, the resubmission to this CRL will be considered to represent a MINOR AMENDMENT, given that the deficiencies have been classified as MINOR. 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 and no new preclinical and clinical studies were requested.

Solving the Ketamine shortage problem in the U.S.

PharmaTher is committed to its overall goal of solving the Ketamine shortage problem in the United States of America and adhering to the FDA's strict manufacturing guidelines. 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. 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.

The outcome with resolving Ketamine's drug shortage issue would be similar to the recent news of Wegovy and Ozempic being removed from the FDA shortage list and compounders have a 60- to 90-day grace period to stop supplying them (see FDA letter).

Unlocking the pharmaceutical potential of Ketamine

With pending FDA approval for Ketamine on the horizon, the Company remains focused on its mission to be a leading innovator and provider of Ketamine to treat unmet medical needs.

It is well-known that Ketamine is an essential medicine used for anesthesia and analgesia (pain relief), listed on the WHO Essential Medicines List, and has been used 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 pain, neurological, and mental health disorders. A published peer-reviewed study on the real-world effectiveness of Ketamine intravenous therapy

demonstrated significant patient improvement for depression, anxiety and suicidal ideation. The potential of Ketamine to make a significant impact on patient lives is immense. PharmaTher, with its innovative approaches and commitment to patient care, is poised to play a pivotal role in making Ketamine available to millions of people globally.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is focused on the development and commercialization of KETARX™ (Ketamine) to fill the unmet medical needs for surgery, pain, mental health, neurological, and medical countermeasures indications. Learn more at **PharmaTher.com**.

For more information about PharmaTher, please contact:

Fabio Chianelli
Chief Executive Officer
PharmaTher Holdings Ltd.
Tel: 1-888-846-3171
Email: info@pharmather.com
Website: www.pharmather.com

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", "provide", 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 six months ended November 30, 2024 dated January 21, 2025, 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.

To view the source version of this press release, please visit
https://www.newsfilecorp.com/release/243010