



## PharmaTher Receives US FDA Approval Goal Date for Ketamine

**The Assigned FDA Approval Goal Date is June 4, 2025**

TORONTO, March 11, 2025 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company hyper-focused on the commercialization of Ketamine, is pleased to announce today that the Company has received an Amendment Acknowledgement Letter ("AAL") from the U.S. Food and Drug Administration ("FDA") for its New Drug Application for Ketamine. In the AAL, the FDA determined this is a minor amendment, meets the criteria for priority review, and assigned an approval goal date of June 4, 2025.

**Fabio Chianelli, Chairman and CEO of PharmaTher, commented:**

"I am very pleased with the new FDA approval goal date of June 4, 2025 for our Ketamine drug. We are focused on solving the shortage issue of Ketamine and becoming the leading supplier of Ketamine to fill the demand gap in the U.S. market."

***Expecting FDA approval of Ketamine on or before June 4, 2025***

As announced on March 3, 2025, PharmaTher provided its resubmission to the complete response amendment and has addressed the deficiencies classified as MINOR in the complete response letter ("CRL") dated October 22, 2024. In the CRL, 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. No additional deficiencies were mentioned in the 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 a new approval goal date of June 4, 2025.

***Solving the Ketamine shortage problem in the U.S.***

PharmaTher is committed to 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.

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 drug shortage list and compounders have a 60- to 90-day grace period to stop supplying them ([see FDA letter](#)).

With ketamine removed from the FDA drug shortage list, the FDA is expected to restrict compound pharmacies from supplying it, opening the door for PharmaTher to fill the demand gap in the U.S. market.

***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 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 significantly impact 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 hyper-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:

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