



## PharmaTher Provides Update on FDA New Drug Application for Ketamine

**PharmaTher expects to submit the MINOR AMENDMENT to the CRL by end-February 2025 and expects a new approval date for a Q2-2025 FDA approval of ketamine**

TORONTO, Feb. 12, 2025 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company seeking FDA approval for ketamine, today announced that the Company is on track to resubmit information to the FDA by end-February 2025. This resubmission, which addresses the deficiencies classified as MINOR in the complete response letter ("CRL") provided by the FDA dated October 22, 2024, is a significant step towards obtaining FDA approval. The Company 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, which achieved 18 months of stability without issue, and no new preclinical and clinical studies were requested.

*PharmaTher is fully committed to the potential of ketamine and is dedicated to its development and approval.*

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) 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 mental health, neurological and pain disorders. 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.

PharmaTher is committed to keeping stakeholders informed and will continue to provide updates as they occur.

### **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. Learn more at [PharmaTher.com](https://www.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 six months ended November 30, 2024 dated January 21, 2025, which is available on the Company's profile at [www.sedarplus.ca](https://www.sedarplus.ca).*

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