PharmaTher CEO Issues Letter to Shareholders

TORONTO, Jan. 06, 2025 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company focused on the development and commercialization of ketamine, announced today that Fabio Chianelli, the Company’s Chairman and Chief Executive Officer, has issued the following letter to shareholders.

Dear Fellow Shareholders:

With the start of a new year, I sincerely thank our loyal shareholders for your continued patience, confidence and support. In 2024, we faced the challenge of two Complete Response Letters (CRL) for our Priority Original Abbreviated New Drug Application for our drug, Ketamine, by the U.S. Food and Drug Administration (FDA). Despite these hurdles, we immediately began to address these issues and are on track to submit our responses to the FDA in February. We expect to receive a new approval date for a Q2-2025 FDA approval. Our journey has been long, but I am very encouraged by our progress and can see the light at the end of the tunnel.

We are ‘All-in’ on Ketamine!

With pending FDA approval for our ketamine drug on the horizon, we remain focused on our 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, and we are enthusiastic to be at the forefront of bringing our ketamine drug to millions of people globally.

As such, I want to share our priorities and expectations for 2025.

Operations. We are committed to controlling costs and ensuring efficient operations. To this end, we utilize third-party consultants and contract manufacturers. Our cash on hand is expected to satisfy our operational needs for 2025. We are focused on obtaining FDA approval for our ketamine drug and initiating commercialization activities, such as commercial manufacturing, global regulatory filings, new business development, and pharmaceutical partnerships.

Commercialization. With the FDA approval nearing, we plan to make our ketamine drug available to pharmaceutical wholesalers, distributors, prescribers, and researchers. We also intend to work with the Defense Health Agency and the Veterans Health Administration. Recently, the VHA approved and will pay for ketamine infusions to treat treatment-resistant depression, PTSD, and chronic pain.

Clinical Development. Our strategy is to pursue strategic clinical trial collaborations with pharmaceutical and biotech companies, research institutions, non-profit research associations and government agencies that conduct clinical research with ketamine for current and new indications. We have been granted FDA orphan designation for Amyotrophic Lateral Sclerosis (ALS), Rett Syndrome and Complex Regional Pain Syndrome (CRPS). We are in a position to support and supply ketamine for clinical studies for rare and near-rare neurological disorders such as Parkinson’s Disease, ALS, Rett Syndrome and CRPS.

Ketamine 2.0. As we enter the commercial stage of our business, we are also laying the foundation for the long term to develop next-generation ketamine and ketamine-like drugs. We have invested in product development programs, such as a ketamine patch and wearable pump, to treat new indications for which ketamine is not approved. Our ketamine patch and wearable pump programs aim to proceed under the 505(b)(2) regulatory pathway for FDA approval. These programs are expected to advance after we receive FDA approval for our ketamine drug. In addition, we are evaluating opportunities with new chemical entities, such as norketamines and the hydroxynorketamines, metaplastogens, and derivatives. We expect to commit to a lead compound in the second half 2025.

We are excited about the prospects for our ketamine drug. We believe it will lead the way for new treatments for people around the world suffering from mental health, neurological and pain disorders. Our enthusiasm for this future is unwavering, and we are committed to realizing this potential.

We believe our future is promising, and we are excited about the journey ahead in 2025. We look forward to continuing this journey with all of you, our valued shareholders.

Sincerely,

Fabio Chianelli
Chairman and CEO
PharmaTher Holdings Ltd.

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.**

For more information about PharmaTher, please contact:

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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", “pending”, “nearing”, “lay”, “prospect”, "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 months ended August 31, 2024 dated October 24, 2024, which is available on the Company's profile at www.sedarplus.ca.

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