PharmaTher Announces Update on FDA New Drug Application for Ketamine

FDA granted a post-complete letter clarification meeting scheduled for December 2, 2024

Company initiated activities to address the deficiencies cited in the CRL

TORONTO, Nov. 19, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, today announced that the FDA granted a post-complete letter clarification meeting (the “Meeting”) scheduled for December 2, 2024.

As previously announced, the Company requested the Meeting in response to the FDA issuing a complete response letter (“CRL”), dated October 22, 2024, for the ketamine Abbreviated New Drug Application, which was assigned a Generic Drug User Fee Amendments of 2022 (“GDUFA”) goal date of October 29, 2024.

The Company has initiated activities to address the deficiencies cited in the CRL. The deficiencies cited in the CRL are 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. 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 Company will announce a proposed timeline for the resubmission to this CRL after the Meeting and 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. 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) for viral infectious diseases and medical countermeasures. 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”, 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.

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.