PharmaTher Announces Update on FDA New Drug Application for Ketamine

FDA provided preliminary responses to questions contained in the clarification only post-CRL meeting scheduled for December 2, 2024

PharmaTher has decided to cancel the meeting as the FDA preliminary responses were satisfactory and do not require further discussion

PharmaTher initiated activities to address the MINOR deficiencies cited in the CRL

TORONTO, Nov. 26, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, today announced that the FDA provided preliminary responses (the “Responses”) to questions contained in the post-complete response letter clarification meeting (the “Meeting”) scheduled for December 2, 2024. PharmaTher has decided to cancel the Meeting as the Responses were satisfactory and do not require further discussion. The Company expects to resubmit information to address the deficiencies classified as MINOR in the complete response letter (“CRL”) by January 2025.

Fabio Chianelli, Chairman and CEO of PharmaTher, commented: “We are very pleased with the responses by the FDA to the clarification questions in our post-CRL meeting request. The FDA has addressed our questions, paving the way for our Ketamine product’s new drug approval. As such, we decided to cancel the meeting, and our team has already begun compiling the responses. We have also initiated additional tests to address the MINOR deficiencies in the CRL, and we expect to submit the MINOR AMENDMENT by January 2025.”

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

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.

The Company 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**.

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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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