PharmaTher Provides Update of its Priority Original Abbreviated New Drug Application for Ketamine

TORONTO, Feb. 12, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, provides an update of its Priority Original Abbreviated New Drug Application (“ANDA”) for Ketamine that was accepted by the U.S. Food and Drug Administration (the “FDA”) and assigned a Generic Drug User Fee Amendments of 2022 (“GDUFA”) goal date of April 29, 2024. The ANDA continues to be under review by the FDA and has provided preliminary thoughts on possible deficiencies identified by Quality. The Company aims to respond to satisfy the preliminary thoughts on possible deficiencies before the goal date. The Company received a waiver from the FDA for bioequivalence studies and has not identified any deficiencies. There can be no assurance the goal date will be met. The FDA may assign an appropriate goal date. The Company will provide updates as they occur.

The Company’s overall goal is to solve the ketamine shortage problem in the U.S. and its ketamine to adhere to the FDA’s strict manufacturing guidelines and FDA-approved prescribing label. Following the anticipated FDA approval and launch in the U.S., the Company aims to pursue international approvals to support the global demand for ketamine. The Company’s long-term strategy is pursuing novel uses and delivery methods of ketamine as a potential treatment for pain, mental health, and neurological disorders.

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 not FDA approved for psychiatric disorders. On October 10, 2023, the FDA published a compounding risk alert describing the potential risks associated with compounded ketamine products for psychiatric disorders, specifically from telehealth providers that provide in-home ketamine services. These compounded ketamine products are not FDA approved.

Ketamine is an essential medicine used for anesthesia and analgesia (pain relief) listed on the WHO Essential Medicines List. In Canada, ketamine has been classified as a Tier 3 drug shortage since February 2023, and Health Canada has approved ketamine for use 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. A recently published new peer-reviewed study on the real-world effectiveness of ketamine intravenous therapy demonstrated significant patient improvement for depression, anxiety and suicidal ideation.

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, and neurological indications. Learn more at **PharmaTher.com.**

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ended November 30, 2023 ("MD&A"), dated January 26, 2024, which is available on the Company's profile at www.sedarplus.ca.

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