PharmaTher Provides Update for Expected FDA Approval of Ketamine

Assigned FDA approval goal date of April 29, 2024, is still on track

TORONTO, Jan. 10, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, is pleased to provide an update for the Company’s lead drug, ketamine (“KETARX™”), as a potential treatment for anesthesia, sedation, pain, mental health, and neurological indications. On September 27, 2023, the Company announced that the U.S. Food and Drug Administration (“FDA”) had accepted the priority original Abbreviated New Drug Application (“ANDA”) for ketamine and assigned an approval goal date of April 29, 2024. The assigned FDA approval goal date is still on track.

Fabio Chianelli, CEO of PharmaTher, commented: “We believe 2024 will be a transformative year for PharmaTher with the expected FDA approval of ketamine having an assigned goal date for approval on April 29, 2024. In anticipation of a potential FDA approval, we are focusing on the commercial scale-up of ketamine in the U.S. and seeking additional international approvals.”

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.

The Company’s overall goal is to solve the ketamine shortage problem in the U.S. and anticipates the commercial launch of ketamine in 2024, and will meet the FDA’s strict manufacturing guidelines and FDA-approved prescribing label. KETARX™ will be produced in the U.S. in a cGMP manufacturing facility that is DEA certified and inspected by domestic and international regulatory agencies, including the FDA and EU EMA.

Following the FDA approval and launch in the U.S., the Company will pursue international approvals to support the global demand for ketamine. 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.

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. In anticipation of a potential FDA approval for ketamine, the Company will allocate funds to the U.S. commercial scale-up and international regulatory approvals, and pause funding for its product and clinical programs, including its microneedle patch and on-body pump systems, Parkinson’s disease, Amyotrophic Lateral Sclerosis, Rett Syndrome, and Complex Regional Pain Syndrome for the first half of 2024. The Company will evaluate these programs quarterly to determine a potential rationale for reviving one or more of them internally or with potential pharmaceutical partners.

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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