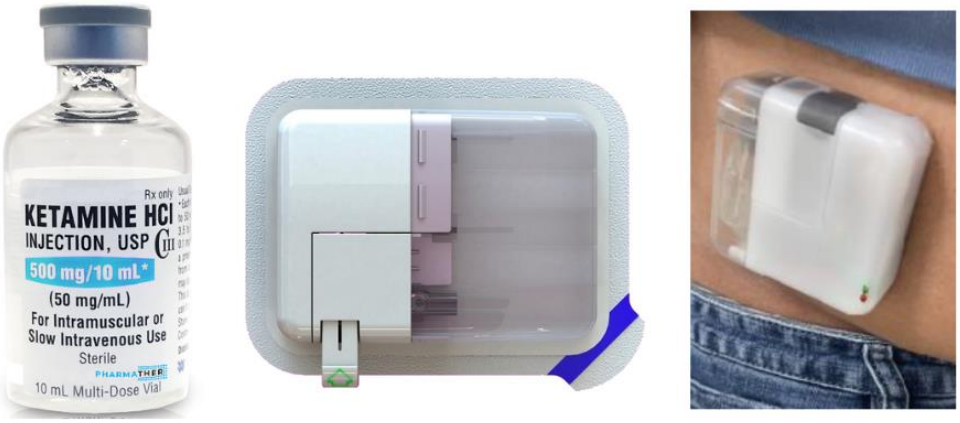
PharmaTher Submits FDA Meeting Package to Discuss 505(b)(2) Pathway for New Drug Application of KETARX™ (Ketamine) On-Body Pump System

TORONTO, February 7, 2023 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a leader in advancing specialty ketamine pharmaceuticals, today submitted its Type B meeting package with the U.S. Food and Drug Administration ("FDA") to discuss the remaining requirements for the KETARX™ On-Body Pump System (subcutaneous racemic ketamine) and submission of a New Drug Application ("NDA") under the 505(b)(2) pathway. PharmaTher aims to leverage its own CMC information, clinical data and available non-clinical and clinical data to submit an NDA by the end of 2023. The meeting date with the FDA is set for March 23, 2023.

Fabio Chianelli, CEO of PharmaTher, commented: "We are in a position to meet with the FDA to obtain guidance on the final requirements for our KETARX™ On-Body Pump System to support a new drug application under the 505(b)(2) pathway. In the short term, we will seek FDA approval for our KETARX™ On-Body Pump System in general anesthesia and sedation for surgical procedures. If successful, this strategy would create a strong foundation in efficiently expanding to mental health, neurological and pain disorders."



Proposed KETARX™ on-body pump kit and application.

Not FDA approved. Not for sale.

PharmaTher aims to obtain FDA approval for the KETARX™ On-Body Pump System for the maintenance of anesthesia and as a supplement to other anesthetic agents in alignment with ketamine's FDA-approved label. In addition, the use of the KETARX™ On-Body Pump System

for sedation during short-term diagnostic and surgical procedures is also being explored to extend the label for specific areas of application or types of procedures where the subcutaneous route of administration would be viable. This approach supports and potentially improves the administration of ketamine in both hospital and clinical settings.

The Company believes that subcutaneous infusion of racemic ketamine via the KETARX™ On-Body Pump System has several advantages over commonly used intravenous ("IV") administration, including decreased requirement for skilled personnel for its administration, reduction in pain and irritation associated with administration, and a reduced risk of systemic infection and other complications seen with IV administration. Subsequently, should the KETARX™ On-Body Pump System obtain FDA approval, it will allow the Company to leverage its regulatory package and clinical data to expand to mental health (i.e. depression, PTSD), neurological (i.e. Parkinson's disease) and pain disorders. This is further supported by the KETARX™ On-Body Pump System's capability to provide either anesthetic or subanesthetic dosing over a defined time period.

Ketamine was approved by the FDA in 1970 and is indicated:

- as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation;
- for the induction of anesthesia prior to the administration of other general anesthetic agents; and
- as a supplement to other anesthetic agents (for the indication of IV or IM induction of anesthesia and maintenance of anesthesia.

Currently, ketamine is emerging as a viable treatment option for depression. In addition, there is a growing off-label use of racemic ketamine for various mental health conditions and pain, requiring IV administration and supervision by healthcare providers in hospitals or certified medical clinics.

There can be no assurance that the FDA will support any potential request for an expedited path to approval or further development for KETARX™ On-Body Pump System.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is a specialty pharmaceutical company focused on developing and commercializing KETARX™ (racemic ketamine) via unique

delivery methods for mental health, neurological and pain disorders. Learn more at **PharmaTher.com.**

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