PharmaTher Signs Exclusive Worldwide License Agreement for Patented Formulation and Production Process of Ketamine and Ketamine Analogs

PharmaTher to file ANDA and 505(b)(2) regulatory submissions with the FDA for novel uses, delivery forms and formulations of ketamine for mental health, neurological and pain disorders

TORONTO, April 12, 2022 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a leader in specialty ketamine pharmaceuticals, is pleased to announce that PharmaTher has entered into an exclusive worldwide license agreement with Gesval S.A., a public limited company incorporated by the University of Liège, Belgium, for the development and commercialization of a patented continuous-flow process technology for the preparation of ketamine and ketamine analogs (the "Ketamine Technology"). The Ketamine Technology strengthens the Company's patent portfolio of ketamine and it will complement the Company's expanding ketamine pharmaceutical pipeline for use in hospitals, clinics and homes.

PharmaTher is developing and commercializing novel uses, delivery forms and formulations of ketamine and ketamine analogs. As part of its short-term product strategy, the Company is developing its own Ketamine Injection and Infusion product to support the Company's expected pivotal clinical studies for Parkinson's disease and Amyotrophic Lateral Sclerosis (Lou Gehrig's disease), future FDA 505(b)(2) regulatory submissions in mental health, neurological and pain disorders, and its commercialization plans in the U.S. via an FDA Abbreviated New Drug Application ("ANDA") for anesthesia and procedural sedation. The Company expects to file the ANDA in Q4-2022 for commercialization in the U.S. In addition, the Company's long-term product strategy is to develop novel ketamine formulations and drug delivery systems, including its patented microneedle patch and proposed wearable pump device for the intradermal and subcutaneous delivery of ketamine, respectively.

Ketamine was approved by the FDA in 1970 and is clinically used for analgesia, sedation, and anesthetic induction. Ketamine is also emerging as a viable treatment option for various mental health, neurological and pain disorders. However, the methods generally used for the production of ketamine are time-consuming and typically based on stepwise macroscopic batch processes resulting in low productivity, reproducibility and flexibility due to poor mixing and heat transfer.

The Ketamine Technology, developed at the Center for Integrated Technology and Organic Synthesis (CiTOS, ULiège) headed by Professor Jean-Christophe Monbaliu, relates to a scalable, safe and efficient continuous-flow process in micro/mesofluidic reactors for the production of ketamine and ketamine analogs, thereby addressing the shortcomings of the ketamine batch processes to improve yield production, reproducibility, purity profile, and requiring smaller footprint for production. In addition to improving the production process of racemic ketamine, the Ketamine Technology provides various methods for synthesizing ketamine analogs (i.e. arylcycloalkylamine derivatives) by using continuous-flow conditions with a drastically improved efficiency relative to batch procedures, which is of paramount importance for developing next-generation ketamines.

"We are excited to advance patented technology for the novel development and production process of ketamine and ketamine analogs from the University of Liège," said Fabio Chianelli, CEO of PharmaTher. "We remain committed to our goal of becoming a leader in the development and commercialization of novel ketamine pharmaceuticals and this license not only strengthens our global patent portfolio for ketamine, but also complements our strategy in commercializing novel uses, delivery forms and formulations of ketamine and ketamine analogs to serve the unmet medical needs for mental health, neurological and pain disorders."

In addition, the Company expects to form partnerships with research labs, ketamine clinics and pharmaceutical companies that are: seeking a secure supply of cGMP ketamine and ketamine products for current portfolios; exploring alternative dosage forms for multiple existing indications; developing novel ketamine analogs; and requiring support to develop and eventually commercialize specific ketamine products for new indications.

Under the terms of the Agreement, PharmaTher gained exclusive worldwide development and commercial rights to an intellectual property portfolio consisting of a granted patent (Europe patent: 3700887B1) and patent applications (PCT/EP2018/097033) titled, "Methods for the preparation of arylcycloalkylamine derivatives" in the U.S., China and Canada.

Consistent with industry standards, PharmaTher paid a one-time fee for entering into the Agreement, and all other future payments are based on clinical trial and revenue milestones reached by PharmaTher.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is focused on the development and commercialization of specialty ketamine pharmaceuticals for mental health, neurological, and pain disorders. Learn more at **PharmaTher.com.**

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