



PharmaTher and Vitruvias Enter Into Collaboration Agreement for Commercialization of KETARX™ (racemic ketamine) in the U.S.

Expected FDA approval for KETARX™ (racemic ketamine) via the ANDA pathway in Q1-2024 and commercial launch in Q2-2024

TORONTO, June 20, 2023 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a commercial-focused specialty pharmaceutical company, is pleased to announce it has entered into a collaboration agreement with Vitruvias Therapeutics, Inc. (“Vitruvias”), a leading U.S. based specialty generic pharmaceutical company, for the commercialization of the Company’s KETARX™ (racemic ketamine) products in the U.S.

In partnership with Vitruvias, KETARX™ will be marketed under [ketamine’s FDA-approved label](#) and in various dosage forms, such as 10 mg/ml, 50 mg/ml and 100 mg/ml, with the option to increase concentration and ready-to-administer applications for the U.S. market. Ketamine is currently on the [FDA’s drug shortage list](#). Outside of the FDA approved indications, ketamine is also being administered in hospitals and clinics to treat various disorders encompassing mental health, neurological and pain.

PharmaTher expects to file its abbreviated new drug application (“ANDA”) for KETARX™ (racemic ketamine) with the FDA in early July and obtain FDA approval in Q1-2024. In anticipation of a potential commercial launch of KETARX™ in Q2-2024, PharmaTher and Vitruvias will work together on pre-commercial launch activities, including marketing, pricing, distribution, managed care, trade relations and sales plans.

Fabio Chianelli, CEO of PharmaTher, commented: “Our highest priority is to obtain regulatory approvals and commercialize KETARX™ (racemic ketamine) worldwide for unmet medical needs. We are focused on building a network of strong commercial partnerships with leading specialty generic companies that are experienced in the marketing, sales and distribution to the hospital, institutional and clinic channels within their territories. We are pleased to partner with Vitruvias for KETARX™ for the U.S. market and believe Vitruvias is the ideal partner to rapidly progress our commercialization goals in the U.S. and unlock new commercial opportunities internationally.”

Founded in 2013, Vitruvias is an experienced specialty pharmaceutical company focused on the marketing and distribution of prescription products within the United States and Puerto Rico.



Vitruvias is led by Carl L. Whatley, Jr., a 40-year sales and marketing veteran in specialty generic pharmaceuticals, and its board members hold executive positions with Perceptive Advisors and JW Asset Management.

Carl L. Whatley, Jr., CEO of Vitruvias, commented: “We are excited about the opportunity to add KETARX™ to our already robust commercial generic product portfolio for the U.S. market. The evolving adoption of ketamine for its current FDA approved use, and potentially other indications excite us on the opportunity to grow the market for ketamine in the U.S., leveraging our strong commercial expertise and infrastructure.”

The collaboration contemplates a definitive agreement whereby PharmaTher would be responsible for regulatory, manufacturing and supply of KETARX™, and Vitruvias would be responsible for the marketing, sales, and distribution to hospitals, institutional and clinics channels in the U.S. market.

About Vitruvias Therapeutics Inc.

Founded in 2013, Vitruvias Therapeutics Inc. is an experienced specialty pharmaceutical company focused on the marketing & distribution of prescription products within the United States and Puerto Rico. Vitruvias is especially active with non-U.S. based generic drug developers and manufacturers who are seeking distribution channels within the U.S. and leverages its expertise in all aspects of the pharmaceutical industry, including product development, licensing, regulatory affairs, marketing, financial analysis, distribution, managed care, trade relations and sales. Visit Vitruvias.com.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) develops and commercializes specialty pharmaceuticals exhibiting growing adoption and permitting novel delivery methods to enhance patient outcomes. The Company’s lead product is KETARX™ (racemic ketamine) to fill the global unmet medical needs for anesthesia, sedation, pain, mental health, and neurological indications. The Company is commercializing PharmaPatch™ (microneedle patch) with its partners to deliver psychedelics and drugs to treat infectious diseases. Learn more at PharmaTher.com.



For more information about PharmaTher, please contact:

Fabio Chianelli
Chief Executive Officer
PharmaTher Holdings Ltd.
Tel: 1-888-846-3171
Email: info@pharmather.com
Website: www.pharmather.com

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This press release contains 'forward-looking information' within the meaning of applicable Canadian securities legislation. These statements relate to future events or future performance. The use of any of the words "could", "would", "intend", "expect", "believe", "will", "projected", "estimated", "potential", "aim", "may", "plan", "proposed", "lead", "toward", and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on PharmaTher Holdings Ltd. (the "Company") current belief or assumptions as to the outcome and timing of such future events. Forward-looking information is based on reasonable assumptions that have been made by the Company at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information. Given these risks, uncertainties and assumptions, you should not unduly rely on these forward-looking statements. The forward-looking information contained in this press release is made as of the date hereof, and Company is not obligated to update or revise any forward-looking information, whether as a result of new information, future 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 and nine months ended February 28, 2023 ("MD&A"), dated April 28, 2023, which is available on the Company's profile at www.sedar.com.

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