



PharmaTher’s Sairiyo Therapeutics Receives Approval to Initiate a Phase 1 Human Clinical Trial of PD-001 (Reformulated Cepharanthine)

TORONTO, August 19, 2024 -- PharmaTher Holdings Ltd. (the “Company” or “PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM), a specialty pharmaceutical company, announced today Sairiyo Therapeutics Inc. (“Sairiyo”), a company that is forty-nine percent (49%) owned by PharmaTher and fifty-one percent (51%) owned by PharmaDrug Inc. (CSE: PHRX) (OTC Pink: LMLLF) (“PharmaDrug”), has received approval by the Australian Human Research Ethics Committee to initiate a first-in-human Phase 1 clinical study (the “Study”) investigating a patented reformulated enteric coated version of oral cepharanthine (“PD-001”) as a potential treatment for [Medical Countermeasures](#) and cancer. PD-001 was previously [awarded a \\$3.4 million contract](#) from the Defense Threat Reduction Agency (DTRA) for the Ebola virus.

Fabio Chianelli, CEO of PharmaTher, commented: “We are very pleased with Sairiyo reaching this major milestone after years of research and development with the aim of unlocking the therapeutic potential of enhanced bioavailability cepharanthine for treating cancers and various medical emergencies such as infectious diseases, terrorist attacks or pandemics.”

Once completed, the Study entitled “Phase 1 Open-label, Single Dose, 3-Way Cross-Over Trial to Assess the Bioavailability and Pharmacokinetics Of 15 mg and 30 mg Capsules Containing Oral Enteric Coated Cepharanthine Dihydrochloride in Comparison to 15 mg Oral Cepharanthine Tablets in Healthy Volunteers”, will support Sairiyo’s submission of an Investigational New Drug application for PD-001 to the U.S. Food and Drug Administration to commence Phase 2 and Phase 3 clinical trials in the United States. Sairiyo’s wholly-owned subsidiary in Australia, Sairiyo Therapeutics Australia Pty Ltd., is the sponsor of the Study.

About PD-001 (Enteric-coated Oral Cepharanthine)

Cepharanthine is a natural product and an approved drug used for more than 70 years in Japan to successfully treat a variety of acute and chronic diseases. In clinical research, cepharanthine has been shown to exhibit multiple pharmacological properties including anti-oxidative, anti-inflammatory, immuno-regulatory, anti-cancer, anti-viral and anti-parasitic effects. However, historically cepharanthine's low oral bioavailability has represented a major obstacle to realizing its full clinical potential.



Compared to generic cepharanthine, PD-001 has been shown in rodent and non-rodent models to possess markedly improved oral bioavailability (more easily absorbed). These findings support the development of an orally administered formulation, and in so doing, removes the undesirable requirement for frequent intravenous dosing to maintain therapeutic levels of drug in circulation. Sairiyo endeavours to develop an efficacious oral therapeutic to potentially improve outcomes for infectious disease and oncology applications.

PD-001 is protected by [US Patent US10576077](#), with a patent expiration date of March 23, 2036.

About Sairiyo Therapeutics Inc.

Sairiyo Therapeutics Inc., which is owned by PharmDrug Inc. (51%) and PharmaTher (49%), is focused on advancing the clinical development of an improved and patented enteric-coated orally bioavailable formulation of cepharanthine (PD-001) as a potential treatment for Medical Countermeasures and oncology.

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. PharmaTher owns 49% of Sairiyo Therapeutics Inc., which focuses on advancing the clinical development of an improved and patented enteric-coated orally bioavailable formulation of cepharanthine (PD-001) for medical countermeasures and cancer. Learn more at PharmaTher.com.

For more information about PharmaTher, please contact:

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Cautionary Statement

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 "closer", "could", "confident", "would", "intend", "expect", "believe", "will", "projected", "estimated", "potential", "aim", "may", "plan", "proposed", "lead", "toward", "anticipate", 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 29, 2024 ("MD&A"), dated April 19, 2024, which is available on the Company's profile at www.sedarplus.ca.

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