



## **PharmaTher’s Sairiyo Therapeutics Submits Clinical Trial Application for Phase 1 Study of Patented Reformulated Cepharanthine**

TORONTO, May 15, 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 submitted to the Australian Human Research Ethics Committee for review and potential approval to initiate a Phase 1 clinical study (the “Study”) of Sairiyo’s patented reformulated enteric coated version of orally bioavailable cepharanthine (“PD-001”) as a potential treatment for infectious diseases and oncology.

The Phase 1 study entitled “Phase 1 Open-label, Single Dose, 3-Way Cross-Over Trial to Assess in Healthy Volunteers the Bioavailability and Pharmacokinetics Of 30 mg and 60 mg Oral Enteric Coated Capsules of Cepharanthine Dihydrochloride in Comparison to 6 mg Oral Cepharanthine Dihydrochloride Tablets”, if approved by the Australian regulators in June 2024, will be a first-in-human study of PD-001. Sairiyo’s wholly-owned subsidiary in Australia, Sairiyo Therapeutics Australia Pty Ltd., is the sponsor of the Study.

In pursuit of its clinical strategy for PD-001, Sairiyo aims to conduct its first-in-human clinical study of PD-001 in Australia to capitalize on drug development incentives in Australia, which could earn a 43.5 percent rebate from the Australian Federal Government’s Research and Development tax incentive program. Upon completion of the clinical study, Sairiyo intends to submit an Investigational New Drug application for PD-001 to the U.S. Food and Drug Administration (FDA) to commence Phase 2 and Phase 3 clinical trials in the United States.

### **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) to treat responsive cancers and infectious disease, including COVID-19.

### **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) to treat responsive cancers and infectious diseases, including COVID-19. Learn more at [PharmaTher.com](http://PharmaTher.com).

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*Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.*

### ***Cautionary Statement***

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