

# PharmaDrug's Sairyo Therapeutics Submits Clinical Trial Application for Phase 1 Study of Patented Reformulated Cepharranthine

Toronto, Ontario--(Newsfile Corp. - May 15, 2024) - PharmaDrug Inc. (CSE: PHRX) (OTC Pink: LMLLF) ("**PharmaDrug**" or the "**Company**"), a specialty pharmaceutical company focused on the research, development and commercialization of controlled-substances and natural medicines such as psychedelics and previously approved drugs, is pleased to announce that Sairyo Therapeutics Inc. ("Sairyo"), a company that is fifty-one percent (51%) owned by PharmaDrug and forty-nine percent (49%) owned by PharmaTher Holdings Ltd. (CSE: PHRM) (OTCQB: PHRRF) ("**PharmaTher**"), has submitted to the Australian Human Research Ethics Committee for review and potential approval to initiate a Phase 1 clinical study (the "Study") of Sairyo's patented reformulated enteric coated version of orally bioavailable cepharanthine ("PD-001") as a potential treatment for infectious diseases and oncology.

Robert Steen, CEO and Chairman of PharmaDrug commented, "We are extremely excited to have cepharanthine on the verge of the next phase in its development and evolution. Having a first in human trial for PD-001 can provide the data needed to augment a FDA phase 2 or phase 3 clinical trial application."

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 Cepharranthine Dihydrochloride in Comparison to 6 mg Oral Cepharranthine Dihydrochloride Tablets," if approved by the Australian regulators in June 2024, will be a first-in-human study of PD-001. Sairyo's wholly-owned subsidiary in Australia, Sairyo Therapeutics Australia Pty Ltd., is the sponsor of the Study.

In pursuit of its clinical strategy for PD-001, Sairyo 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, Sairyo 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 Cepharranthine)

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, immunoregulatory, anti-cancer, anti-viral and anti-parasitic effects<sup>1,2</sup>. 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. Sairyo 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 PharmaDrug Inc.

PharmaDrug is a specialty pharmaceutical company focused on the research, development and commercialization of controlled-substances and natural medicines such as psychedelics and previously approved drugs. PharmaDrug owns 51% of Sairyo Therapeutics ("Sairyo"), a biotech company that specializes in researching and reformulating established natural medicines with a goal of bringing them through clinical trials and the associated regulatory approval process in the US and Europe. Sairyo is currently developing its patented reformulation of cepharanthine, a drug that has shown substantial third party validated potential for the treatment of infectious disease and rare cancers. Sairyo is also conducting R&D in the psychedelics space for the treatment of non-neuropsychiatric conditions. PharmaDrug also owns 100% of SecureDose Synthetics Inc. ("SecureDose"), a pharmaceutical research and development company focused on the development of synthetic formulations of currently existing drugs for potential commercialization and distribution.

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**References:**

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