

PharmaDrug's Sairyo Therapeutics Receives Approval to Initiate Phase 1 Clinical Trial of Patented Reformulated Cepharranthine

Toronto, Ontario--(Newsfile Corp. - August 19, 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 on the 12th of August 2024, 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 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](#)¹.

Robert Steen, CEO of PharmaDrug commented, "We are extremely excited to have achieved this significant milestone for PD-001. This is the product of several years of research and development with the aim of unlocking the therapeutic potential of our patented enhanced bioavailability cepharanthine to potentially treat cancers, infectious diseases and viral 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 Sairyo's submission of 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. Sairyo's wholly- owned subsidiary in Australia, Sairyo 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, immunoregulatory, anti-cancer, anti-viral and anti-parasitic effects^{2,3}. 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. Sairiyo 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. Sairiyo 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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Forward-looking information is subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements of the Company to be materially different from those expressed or implied by such forward-looking information. Such risks and other factors may include, but are not limited to: general business, economic, competitive, political and social uncertainties; general capital market conditions and market prices for securities; the actual results of the Company's future operations; competition; changes in legislation affecting the Company; the ability to obtain and maintain required permits and approvals, the timing and availability of external financing on acceptable terms; lack of qualified, skilled labour or loss of key individuals..

A description of additional risk factors that may cause actual results to differ materially from forward-looking information can be found in the Company's disclosure documents on the SEDAR+ website at www.sedarplus.ca. Although the Company has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking information, there may be other factors that cause results not to be as anticipated, estimated or intended. Accordingly, readers should not place undue reliance on forward-looking information. Readers are cautioned that the foregoing list of factors is not exhaustive. Readers are further cautioned not to place undue reliance on forward-looking information as there can be no assurance that the plans, intentions or expectations upon which they are placed will occur. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated.

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References:

¹<https://www.swri.org/press-release/southwest-research-institute-texas-biomedical-research-institute-awarded-34-million>

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