PharmaDrug's Sairiyo Therapuetics Announces Initiation of Study Start-Up Activities and Design for Clinical Trial of PD-001 (Patented Reformulated Cepharanthine) for Viral Infectious Diseases

Toronto, Ontario--(Newsfile Corp. - September 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 announcing it has initiated start-up activities for its first clinical study of its patented enteric-coated cepharanthine formulation ("PD-001") as a potential treatment for viral infectious diseases. As announced on August 19, 2024, Sairiyo Therapeutics Inc. ("Sairiyo"), a company that is fifty-one percent (51%) owned by PharmaDrug and fourty-nine percent (49%) owned by PharmaTher Holdings Ltd. (CSE: PHRM) (OTCQB: PHRRF) ("**PharmaTher**"), received approval by the Australian Human Research Ethics Committee to initiate a first-in-human Phase 1 clinical study (the "Study") to support PD-001 as a potential treatment for viral infectious diseases. Study start-up activities include the manufacturing scale-up of PD-001 and the evaluation and final selection of potential clinical sites and a clinical research organization to assist in the project management, medical monitoring, data management and clinical packaging of the Study.

The Study, designed and titled, "Phase 1 Open-label, Single Dose, 3-Way Cross-Over Trial to Assess in Healthy Volunteers 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", has a primary objective to assess the comparative bioavailability of oral PD-001 and oral cepharanthine tablets. Additional study objectives include evaluation of other comparative pharmacokinetic, safety and tolerability information of the two drug formulations. The proposed dosages for PD-001 represent an 8-fold and 4-fold safety factor of the NOAEL determined in a previous pre-clinical toxicity study in rats. The Study duration will be up to 49 days including the screening period, a 7-day washout period between doses and the time between the last blood sampling and after the last dose and final examination tests. It is reasoned that oral PD-001 is capable of achieving better oral pharmacokinetics than oral generic cepharanthine tablets and have the same or better safety. It is expected that a total of 15 volunteers will be enrolled in the trial to obtain a targeted number of 12 volunteers completing the Study.

Robert Steen, CEO of PharmaDrug, commented, "We have begun planning for the phase 1 study in Australia. Given cepharanthine's long history of being a safe and approved drug in Japan for over 70 years, we are fairly confident of its safety profile, but its therapeutic utility is limited due to its low bioavailability. Our patented enteric-coated version of cepharanthine aims to solve the drug's limitations and we look to have the study confirm PD-001's higher bioavailability to provide us with important data that we can use for future phase 2 studies in viral infectious diseases. The acquired data can also help attract the interest of potential pharmaceutical partners or other institutional investors."

Upon successful completion of the Study, Sairiyo will seek to obtain FDA acceptance to advance the clinical development of PD-001 in a Phase 2 clinical study for a specific viral infectious disease. The objective is to partner with a pharmaceutical company towards FDA approval and seek continuing government support, including approaching the Biomedical Advanced Research and Development Authority having a focus on public health medical emergencies such as pandemic influenza and emerging infectious diseases.

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[1,2]. 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 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 Sairiyo Therapeutics ("Sairiyo"), 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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References:

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