PharmaDrug's Sairiyo Therapuetics Provides Strategic Plans to Advance PD-001 (Patented Reformulated Cepharanthine) for Viral Infectious Diseases

Toronto, Ontario--(Newsfile Corp. - August 28, 2024) - PharmaDrug Inc. (CSE: PHRX) (OTC: 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 its strategic plans to advance the clinical development of its patented enteric-coated Cepharanthine formulation ("PD-001") 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. This builds on PD-001 previously being awarded a $3.4 million contract from the Defense Threat Reduction Agency for the Ebola virus. Upon successful completion of the Study, Sairiyo will seek to advance the clinical development of PD-001 towards FDA approval through pharmaceutical partnerships or 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.

Robert Steen, CEO of PharmaDrug commented, "We are excited to finally be ready to advance PD-001 for clinical development as an anti-viral. In a world that we believe needs a larger arsenal to combat viral infectious diseases, cepharanthine has been highlighted in several studies and publications for the potential treatment of several viruses ranging from Ebola, to SARS/COVID and even the Zica Virus. The limiting factor has been its bioavailability. We believe that PD-001, with its patented enhanced bioavailability of cepharanthine, can potentially serve as a multi-indication anti-viral. We look forward to further explore cepharanthine's therapeutic prospects for a wide spectrum of viral infectious diseases including Mpox."

PD-001's potential for viral infectious diseases

Cepharanthine is a Japanese approved drug used to successfully treat a variety of acute and chronic diseases. Cepharanthine's anti-inflammatory, antibacterial, antioxidant, antihemolytic and immunomodulatory effects have recently made it a promising therapeutic molecule for viral and/or infectious diseases[1].

Cepharanthine has been shown in the literature to have antiviral activity against the coronavirus (e.g. COVID-19, SARS-CoV, MERS Middle East Respiratory virus)[2-4], HIV-1 virus[5], hepatitis B virus[6], herpes zoster virus[7], T-lymphotropic virus[8], nipah virus[9], ebola virus and Zika virus[10].

Cepharanthine's limitation

Cepharanthine's current commercial formulation in Japan is a simple tablet for oral administration. It is provided in large doses due to its low solubility in water and bioavailability. However, the potential for Cepharanthine as an antiviral therapeutic molecule makes it important to explore new dosage forms[1]. In a recent publication, Cepharanthine effectiveness in the treatment of SARS-CoV-2 infection was clearly demonstrated; however, the low oral bioavailability suggested intravenous administration was the likely way to support further clinical application[11].

PD-001's solution to Cepharnathine

The clinical development of PD-001 is aimed at improving the solubility, stability, release profile, and ultimately bioavailability of the drug, positioning it to be evaluated further as an antiviral therapy. 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 oral and intravenous dosing to maintain therapeutic levels of drug in circulation. PD-001 is protected by US Patent US10576077, with a patent expiration date of March 23, 2036.

The Company would like to make it clear that is not making any express or implied claims that its product (cepharanthine) has the ability to treat, eliminate or cure any infectious diseases at this time.

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[12,13]. 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.

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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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