

# PharmaDrug's Sairiyo Successfully Demonstrates Ability to Manufacture Cepharanthine (PD-001) for Human Clinical Studies

## Company to pursue regulatory filing for Phase I/II clinical study

Toronto, Ontario--(Newsfile Corp. - February 14, 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 provide an update on the development activities of Sairiyo Therapeutics Inc. ("**Sairiyo**"), a 51% owned subsidiary of the Company. The update relates to Sairiyo's patented reformulated enteric coated version of orally bioavailable cepharanthine (PD-001) as a potential treatment for oncology and infectious diseases. The technical transfer and development activities with Genvion Corporation are completed and successfully demonstrated the ability to manufacture clinical GMP manufacturing batches of PD-001 to support future filings to Australia's Therapeutic Goods Administration (TGA) and the Food and Drug Administration (FDA) in the United States. This announcement is made in conjunction with PharmaTher Holdings Ltd, a 49% shareholder of Sairiyo.

Robert Steen, CEO and Chairman of PharmaDrug commented, "We are extremely excited to reach this milestone in the development of PD-001. We will immediately begin taking the steps required to set up the appropriate infrastructure and partner relationships in Australia for the purposes of a potential human clinical trial. We have already begun to work on an application and expect to be able to submit it to the proper channels in the next quarter."

The successful completion of analytical method establishment, manufacturing protocol development and materials handling strategies for PD-001 API and Drug Product enabled the manufacturing of a feasibility batch. Successful completion of the feasibility batch demonstrated appropriateness of the manufacturing process and material evaluation approaches in support of scale up activities for future clinical research needs. On going stability studies are being conducted to support product performance and shelf-life determination.

Manufacturing of product for clinical studies is scheduled for the second quarter of 2024. These materials are intended to support potential Phase 1 and 2 clinical trials of PD-001 for oncology and infectious diseases. The Company has commenced working on a regulatory application to the TGA for an in human safety trial in Australia.

### **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<sup>1,2</sup>. However, historically cepharanthine's low oral bioavailability has represented a major obstacle to realizing its full clinical potential.

Sairiyo is focused on advancing the clinical development of an improved and patented enteric-coated oral formulation of cepharanthine (PD-001) to treat responsive cancers and COVID-19. 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.

## **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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