

# PharmaDrug's Sairiyo Therapeutics Announces Successful Completion of Stability Study of PD-001 (Patented Reformulated Cepharanthine) to Support Use in Phase 1 Study for Viral Infectious Diseases

Toronto, Ontario--(Newsfile Corp. - October 31, 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 successfully completed its stability study of its patented enteric-coated cepharanthine formulation ("PD-001"), which supports the manufacturing of clinical trial material of PD-001 for use in the Company's first-in-human Phase 1 clinical study (the "Study") 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 forty-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.

The six-month accelerated condition stability study (40 degrees Celsius and 75% relative humidity) was completed by Genvion Corporation, the Company's contract development and manufacturing organization. The study demonstrated that PD-001 showed acceptable change for all measured parameters indicating that the product is stable as active in bottle or encapsulated active in bottle. Genvion Corporation will be manufacturing PD-001 clinical trial material for the Study.

Robert Steen, CEO of PharmaDrug commented, "The stability study gives us the confidence that our manufacturing strategy is appropriate to move forward with scale up and GMP activities to support clinical trials. With the study now complete, we can finally look to finalize plans to begin our phase 1 study 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.

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.

For further information, please contact:

Robert J. Steen, Chairman and CEO

[rob@pharmadrug.ca](mailto:rob@pharmadrug.ca)

(416) 400-7086

Caution Regarding Forward-Looking Information:

THE CANADIAN SECURITIES EXCHANGE HAS NOT REVIEWED NOR DOES IT ACCEPT RESPONSIBILITY FOR THE ADEQUACY OR ACCURACY OF THIS RELEASE.

*This news release may contain forward-looking statements and information based on current expectations. These statements should not be read as guarantees of future performance or results of the Company. Forward-looking statements in this press release relate to the potential for cepharanthine as a treatment for Mpox and the development of the Company's business. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by such statements.*

*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](http://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.*

*The Company's securities have not been registered under the U.S. Securities Act of 1933, as amended (the "U.S. Securities Act"), or applicable state securities laws, and may not be offered or*

*sold to, or for the account or benefit of, persons in the United States or "U.S. Persons", as such term is defined in Regulations under the U.S. Securities Act, absent registration or an applicable exemption from such registration requirements. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities in the United States or any jurisdiction in which such offer, solicitation or sale would be unlawful.*

*Forward-looking information contained in this press release is expressly qualified by this cautionary statement. The forward-looking information contained in this press release represents the expectations of the Company as of the date of this press release and, accordingly, are subject to change after such date. However, the Company expressly disclaims any intention or obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as expressly required by applicable securities law.*

**References:**

1. Saito T, Hikita M, Kohno K, Tanimura H, Miyahara M, Kobayashi M. Enhanced expression of the multidrug resistance gene in vindesine-resistant human esophageal cancer cells. *Oncology*. 1994 Sep-Oct;51(5):440-5. doi: 10.1159/000227380. PMID: 8052486.
2. Zhou P, Zhang R, Wang Y, Xu D, Zhang L, Qin J, Su G, Feng Y, Chen H, You S, Rui W, Liu H, Chen S, Chen H, Wang Y. Cepharanthine hydrochloride reverses the *mdr1* (P-glycoprotein)-mediated esophageal squamous cell carcinoma cell cisplatin resistance through JNK and p53 signals. *Oncotarget*. 2017 Nov 27;8(67):111144-111160. doi: 10.18632/oncotarget.22676. Erratum in: *Oncotarget*. 2021 Jan 05;12(1):61-62. PMID: 29340044; PMCID: PMC5762312.



To view the source version of this press release, please visit <https://www.newsfilecorp.com/release/228457>