

# PharmaDrug Initiates Preclinical Study of Cepharranthine to Both Broaden Its Cancer Scope and to Streamline Its Strategy for Esophageal Cancer

Toronto, Ontario--(Newsfile Corp. - May 6, 2021) - PharmaDrug Inc. (CSE: BUZZ) (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, cannabis and naturally-derived approved drugs, is pleased to announce that it has entered into a service agreement with a respected contract research organization (CRO) with deep expertise in preclinical oncology model development and drug testing, to evaluate the Company's patented enteric-coated formulation of Cepharranthine ("PD-001") in a broad panel of human cancers.

"We are focused on advancing the clinical development of our novel Cepharranthine formulation that not only has significant potential for infectious diseases, but also in select rare forms of cancer with high unmet medical needs," said Daniel Cohen, CEO of PharmaDrug. "Our research and development strategy to identify highly probable uses of PD-001 in select cancer indications will allow us to de-risk and accelerate development of preclinical and clinical studies while building core competencies and scientific data for future partnering opportunities with pharmaceutical companies."

Based on multiple, positive preclinical data sets<sup>1,2,3</sup> and a recent decision from the FDA to grant Orphan Drug Designation (ODD) for Cepharranthine in the treatment of esophageal cancer, the Company remains committed to fully exploring this clinical opportunity. However, in parallel, the Company will undertake efforts to confirm and expand on Cepharranthine's noted benefit in previously examined cancers, while also assessing potential benefit across a panel of untested cancer types.

The Company's current study, which will examine the anti-cancer properties of PD-001 in a large panel of solid and liquid cancer cell types, will be conducted under study conditions that will facilitate valid head-to-head comparisons of relative drug potency. A planned follow up study will use data generated from the first study to examine the benefit of PD-001 alone (monotherapy) or when combined with relevant first and second-line chemotherapy drugs. In most cases, adoption of any novel anti-cancer therapeutic occurs as an 'add-on' to an established multidrug standard of care. Development of chemoresistance after repeated and prolonged exposure to chemotherapy remains a significant clinical challenge<sup>4</sup>. Cepharranthine has been shown in preclinical efficacy models to restore cancer cell sensitivity to multiple unrelated classes of chemotherapy. Collectively the studies being undertaken by the Company aim to identify and provide focus on novel opportunities in oncology by revealing optimal drug combinations, situations where PD-001 can prevent, lessen, or reverse chemoresistance, and/or provide additive/synergistic benefit to existing treatments. Data collected during these studies will be used to help inform the Company's downstream clinical development efforts while also potentially creating opportunities to secure additional intellectual property around any novel findings.

## **About PD-001 (Enteric-coated Cepharranthine)**

Cepharranthine 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, Cepharranthine has been shown to exhibit multiple pharmacological properties including anti-oxidative, anti-inflammatory, immunoregulatory, anti-cancer, anti-viral and anti-parasitic properties<sup>5</sup>. However, historically Cepharranthine's low oral bioavailability has represented a major obstacle to realizing its full clinical potential.

The Company is focused on advancing the clinical development of an improved oral formulation of Cepharranthine (PD-001) to treat rare cancers and infectious diseases. Compared to generic

Cepharanthine, PD-001 has been shown in rodent and non-rodent models to possess markedly superior 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.

## **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, cannabis and naturally-derived approved drugs. The Company owns 80% of Pharmadrug Production GmbH, a German medical cannabis distributor, with a Schedule I European Union narcotics license and German EuGMP certification allowing for the importation and distribution of medical cannabis to pharmacies in Germany and throughout the EU. The Company also owns 100% of Super Smart, a Dutch company building a modern adult use psychedelic retail business with an elevated and educational focus. PharmaDrug recently acquired Sairyo Therapeutics, a biotech company that specializes in researching and reformulating established natural medicines with a goal of bringing them through regulatory and research driven clinical trials.

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## **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 press release contains "forward-looking information" within the meaning of applicable securities legislation. All statements, other than statements of historical fact, included herein are forward-looking information. Generally, forward-looking information may be identified by the use of forward-looking terminology such as "plans", "expects" or "does not expect", "proposed", "is expected", "budgets", "scheduled", "estimates", "forecasts", "intends", "anticipates" or "does not anticipate", or "believes", or variations of such words and phrases, or by the use of words or phrases which state that certain actions, events or results may, could, would, or might occur or be achieved. In particular, this press release contains forward-looking information in relation to: the timing of the proposed non-clinical and clinical manufacturing of Cepharanthine for the Company's rare cancer and infectious diseases programs; the ability to expedite development timelines by leveraging SwRI's existing Cepharanthine preclinical data sets and manufacturing know-how; the ability to advance clinical development of an improved oral formulation of Cepharanthine to treat rare cancers and infectious diseases; the ability to obtain applicable approval for the use of Cepharanthine to treat esophageal cancer; the timing and potential results of the Company's plan to initiate high throughput studies to screen a large panel of additional cancers; the Company's plans to evaluate the benefit of its novel oral formulation of Cepharanthine in an animal model of SARS-CoV-2 infection and its proposed discussions with regulators regarding same. This forward-looking information reflects the Company's current beliefs and is based on information currently available to the Company and on assumptions the Company believes are reasonable. These assumptions include, but are not limited to the ability of the Company to successfully execute on its plans for the Company and Sairyo; the ability to complete the studies referenced herein and the results thereto; the ability to obtain required regulatory approvals and the Company's continued response and ability to navigate the COVID-19 pandemic being consistent with, or better than, its ability and response to date.*

*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; risks related to the COVID-19 pandemic including various recommendations, orders and measures of governmental authorities to try to limit the pandemic, including travel restrictions, border closures, non-essential business closures, service disruptions, quarantines, self-isolations, shelters-in-place and social distancing, disruptions to markets, economic activity, financing, supply chains and sales channels, and a deterioration of general economic conditions; and a deterioration of financial markets that could limit the Company's ability to obtain external financing.*

*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.sedar.com](http://www.sedar.com). 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.*

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