



## **WPD Pharmaceuticals Announces FDA Application Under The Orphan Drug Act Was Submitted By License Partner for Brain Cancer Drug, Berubicin**

*Previously awarded approximately \$6 million reimbursement grant for brain cancer drug, Berubicin, by the European Union*

**Vancouver, British Columbia – April 24, 2020 – WPD Pharmaceuticals Inc.** (CSE: WBIO)(FSE: 8SV1) (the “**Company**” or “**WPD**”) a clinical stage pharmaceutical company is pleased to announced that its license partner, CNS Pharmaceuticals, Inc. (NASDAQ: CNSP) (“**CNS**”) filed an application with the U.S. Food and Drug Administration (“**FDA**”) under the Orphan Drug Act to receive Orphan Drug Designation (“**ODD**”) for its brain cancer drug candidate, Berubicin. WPD was previously awarded a reimbursement grant of approximately \$6 million by the Polish National Center for Research and Development for a Phase 2 study of Berubicin, in Poland.

Under a prior developer, Berubicin, then known as RTA 744, was granted ODD by the FDA for the treatment of malignant gliomas. In the prior developer's Phase 1 trial of Berubicin, 44% of the patients received a significant clinical benefit from their treatment. Additionally, one patient in this study experienced a complete response to his treatment with Berubicin and remains alive today, 14 years after treatment.

**Mariusz Olejniczak, CEO of WPD commented,** *"In collaboration with our License partner, CNS, we are excited to announce this FDA submission for Berubicin, as it would if granted, award special status and accelerate the development of the drug candidate to treat glioblastoma, one of the world's most aggressive forms of cancer. We look forward to providing additional information on the initiation of a Phase II trial utilizing the \$6 million grant to evaluate the effect of Berubicin on patients with glioblastoma later this year."*

The Orphan Drug Act (“**ODA**”) provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status").

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Due to small patient numbers, treatment for these rare diseases would not be considered economically feasible without government programs to support their economic viability. Orphan Drug Designation would qualify Berubicin for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees. The receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval. There is no assurance that ODD status will be approved.

**About Berubicin**

Berubicin is an anthracycline, a class of anticancer agents that are among the most powerful chemotherapy drugs and effective against more types of cancer than any other class of chemotherapeutic agents. Anthracyclines are designed to utilize natural processes to induce deoxyribonucleic acid (DNA) damage in targeted cancer cells by interfering with the action of topoisomerase II, a critical enzyme enabling cell proliferation. Berubicin treatment of brain cancer patients appeared to demonstrate positive responses that include one durable complete response in a Phase 1 human clinical trial conducted by Reata Pharmaceuticals, Inc. (NASDAQ: RETA), a US\$5.25Bn pharmaceuticals company.

### **About WPD Pharmaceuticals**

WPD is a biotechnology research and development company with a focus on oncology, namely research and development of medicinal products involving biological compounds and small molecules. WPD has 10 novel drug candidates with 4 that are in clinical development stage. These drug candidates were researched at institutions including the Mayo Clinic and Emory University, and WPD currently has ongoing collaborations with Wake Forest University and leading hospitals and academic centers in Poland.

WPD has entered into license agreements with Wake Forest University Health Sciences and sublicense agreements with Moleculin Biotech, Inc. and CNS Pharmaceuticals, Inc., respectively, each of which grant WPD an exclusive, royalty-bearing sublicense to certain technologies of the licensor. Such agreements provide WPD with certain research, development, manufacturing and sales rights, among other things. The sublicense territory from CNS Pharmaceuticals and Moleculin Biotech includes 31 countries in Europe and Asia, including Russia.

### **On Behalf of the Board**

*'Mariusz Olejniczak'*

Mariusz Olejniczak  
CEO, WPD Pharmaceuticals

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### **Cautionary Statements:**

*Neither the Canadian Securities Exchange nor the Investment Industry Regulatory Organization of Canada accepts responsibility for the adequacy or accuracy of this release.*

*This press release contains forward-looking statements. Forward-looking statements are statements that contemplate activities, events or developments that the Company can develop effective drugs, that some of its drug candidates may be fast tracked with orphan drug designation; and that we will receive partial reimbursement for certain of its research. Factors which may prevent the forward looking statement from being realized include that competitors or others may successfully challenge a granted patent and the patent could be rendered void; that results obtained in limited trials may not be able to be duplicated in the general population; that we are unable to raise sufficient funding for our research; that we may not*

*meet the requirements to receive the grants awarded; that ODD status is rejected by the FDA; that the EU changes the terms of the grants; that our drugs don't provide positive treatment, or if they do, the side effects are damaging; competitors may develop better or cheaper drugs; and we may be unable to obtain regulatory approval for any drugs we develop. Readers should refer to the risk disclosure included from time-to-time in the documents the Company files on SEDAR, available at [www.sedar.com](http://www.sedar.com). Although the Company believes that the assumptions inherent in these forward-looking statements are reasonable, they are not guarantees of future performance and, accordingly, they should not be relied upon and there can be no assurance that any of them will prove to be accurate. Finally, these forward-looking statements are made as of the date of this press release and the Company assumes no obligation to update them except as required by applicable law.*