

## WPD and CNS Pharmaceuticals Announce Positive Opinion of the Polish Central Ethics Committee for the WPD-201 Study and Central IRB Study Level Approval for the CNS-201 Study

WPD Pharmaceuticals plans to initiate a Berubicin Phase 2 adult GBM trial in the first half of 2021 and a multicenter pediatric malignant glioma Phase 1 clinical trial in 2021

CNS Pharmaceuticals plans to initiate a Berubicin adult GBM trial in Q1 2021

HOUSTON, Feb. 18, 2021 (GLOBE NEWSWIRE) -- **WPD Pharmaceuticals (CSE:WBIO) (8SV1.F)** ("WPD") and **CNS Pharmaceuticals, Inc. (NASDAQ: CNSP)** ("CNS" or the "Company"), biopharmaceutical companies specializing in the development of novel treatments for primary and metastatic cancers of the brain and central nervous system, today announced that WPD Pharmaceuticals received a positive opinion of the Lower Silesian Medical Chamber Ethics Committee in Wrocław, Poland for its planned upcoming Berubicin clinical trial in adults with Glioblastoma Multiforme (GBM) under the WPD-201 Clinical Trial Protocol. CNS Pharmaceuticals has received study level Central IRB Approval from the Central IRB for the CNS-201 Clinical Trial Protocol.

[Berubicin](#) is the Company's novel anthracycline candidate for the treatment of a number of serious oncology indications, currently in development for the treatment of GBM. CNS entered into a sublicense agreement with WPD in November 2019, which provided WPD the commercial rights in select territories in Europe and Asia to Berubicin.

**Mariusz Olejniczak, CEO of WPD** comments, *"This is an important step for WPD from both a project and sublicense agreement point of view. After receiving the positive opinion from the Central Ethics Committee, we are planning to submit our application to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, which is the Polish equivalent of the FDA. We hope to receive approval within three months from submission, dependent on if we receive any questions or requests from the President of the Office. We are planning for our sites to start recruiting patients soon after approval is received. Information about our sites will be published both on [clinicaltrials.gov](#) and in the European database. During the review process, we will start preparing submissions to Ethic Committee and Competent Authority (equivalent of FDA) in one country outside of Poland."*

*"We are pleased for WPD to achieve this key milestone and are encouraged by their continued execution in furthering the development of Berubicin,"* commented **John Climaco, CEO of CNS Pharmaceuticals**. *"Importantly, we believe WPD's Ethics Committee approval of the WPD-201 Clinical Trial Protocol coupled with our recent IND approval and Central IRB Study Level approval, position us one step closer to collaboratively initiating three clinical trials for Berubicin during 2021. We look forward to continuing our trial preparations, as well as WPD's planned submissions to the Polish Competent Authority."*

Following the sublicense agreement, WPD was subsequently awarded a reimbursement grant for further development of Berubicin that was valued at \$6 million upon the date of the grant from the Polish National Center for Research and Development under Smart Growth Operational Program 2014-2020 co-financed by the European Union. WPD plans to initiate both a multicenter Berubicin Phase 2 adult GBM trial in the first half of 2021 and a multicenter pediatric malignant glioma Phase 1 clinical trial in 2021. Roughly 60% of the program budget is expected to be funded by the reimbursement grant.

CNS Pharmaceuticals has received approval to proceed with their previously submitted Investigational New Drug (IND), from the U.S. Food and Drug Administration (FDA) for Berubicin in the treatment of GBM. The Company plans to initiate its Phase 2 trial evaluating the efficacy and safety of Berubicin in the treatment of adults with GBM who have failed first-line therapy in the first quarter of 2021. The Company has also received Central IRB study level approval for the U.S. portion of the adult GBM study.

### About Berubicin

Berubicin is an anthracycline, a class of drugs among the most powerful chemotherapy drugs and effective against more types of cancer than any other class of chemotherapeutic agents. Anthracyclines are designed to damage the DNA of targeted cancer cells by interfering with the action of the topoisomerase II, a critical enzyme enabling cell proliferation. Berubicin was developed at the MD Anderson Cancer Center (MDACC), the world's largest cancer research facility. Berubicin appeared to demonstrate one Durable Complete Response in a Phase I human clinical trial conducted by a prior developer.

### About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals is developing novel treatments for primary and metastatic cancers of the brain and central nervous system. Its lead drug candidate, Berubicin, is proposed for the treatment of glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer. CNS holds a worldwide exclusive license to the Berubicin chemical compound and has acquired all data and know-how from Reata Pharmaceuticals, Inc. related to a completed Phase 1 clinical trial with Berubicin in malignant brain tumors, which Reata conducted in 2006. In this trial the overall response rate of stable disease or better was 44%. This 44% disease control rate was based on 11 patients (out of 25 evaluable patients) with stable disease, plus

responders. One patient experienced a durable complete response and remains cancer-free as of Feb. 20, 2020. These Phase 1 results represent a limited patient sample size and, while promising, are not a guarantee that similar results will be achieved in subsequent trials. By the end of 2020, CNS expects to commence a Phase 2 clinical trial of Berubicin for the treatment of GBM in the U.S., while a sub-licensee partner undertakes a Phase 2 trial in adults and a first-ever Phase 1 trial in pediatric GBM patients in Poland. Its second drug candidate, WP1244, is a novel DNA binding agent that has shown in preclinical studies that it is 500 times more potent than the chemotherapeutic agent daunorubicin in inhibiting tumor cell proliferation.

For more information, please visit [www.CNSPharma.com](http://www.CNSPharma.com).

## **About WPD Pharmaceuticals**

WPD is a biotechnology research and development company with a focus on oncology and virology, namely research and development of medicinal products involving biological compounds and small molecules. WPD has licensed in certain countries 10 novel drug candidates with 4 that are in clinical development stage. These drug candidates were researched at medical institutions, 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 compounds for about 30 countries, mostly in Europe. Such agreements provide WPD with certain research, development, manufacturing and sales rights and obligations, among other things.

For more information, please visit [wpdpharmaceuticals.com](http://wpdpharmaceuticals.com).

## **On Behalf of the Board**

*'Mariusz Olejniczak'*  
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## **Forward Looking Statements**

*This document contains forward-looking statements. Forward-looking statements are statements that contemplate activities, events or developments that the Company anticipates will or may occur in the future. Forward-looking statements in this press release include timing for clinical trials for our drug candidates; that a large portion of our program budget will be refunded by research and other grants and that WPD's drugs could be developed into novel treatments for cancer and other diseases. These forward-looking statements reflect the Company's current expectations based on information currently available to management and are subject to a number of risks and uncertainties that may cause outcomes to differ materially from those projected. Factors which may prevent the forward looking statement from being realized is that competitors or others may successfully challenge granted patents and the patents could be rendered void; that we are unable to raise sufficient funding for our research; that we may not meet the requirements to receive the grants awarded; that our drugs don't provide positive treatment, or if they do, the side effects are damaging; competitors may develop better or cheaper drugs; we may be unable to obtain regulatory approval for any drugs we develop; and we may otherwise be unable to carry out our business plans. 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 document and the Company assumes no obligation to update them except as required by applicable law.*