

WPD Pharmaceuticals Plans to Commence Phase Ib/II Study of Berubicin for the Treatment of Glioblastoma in 2H 2021

VANCOUVER, British Columbia, June 28, 2021 (GLOBE NEWSWIRE) -- **WPD Pharmaceuticals Inc.** (CSE: WBIO)(FSE: 8SV1) (the “**Company**” or “**WPD**”) a clinical-stage pharmaceutical company, today provided an update on its Berubicin drug candidate clinical development program for the treatment of glioblastoma multiforme (GBM).

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.

Phase II Adult Glioblastoma Clinical Trial

Berubicin’s Phase I clinical trial in adults, the first time it was tested in humans, yielded promising results with 44% of the patients with glioblastoma multiforme (GBM) showing a clinical response of stable disease or better based on limited clinical data. This response rate rises to 49% in Avastin-naïve patients. Importantly, Berubicin has shown evidence of improved overall survival in a patient population that currently has a dismal median survival rate of only 14.6 months from diagnosis.

WPD expects final approval from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products shortly and anticipates starting a Phase II Trial in the second half of 2021. Based on the promising Phase I results, WPD plans to commence a multicenter, open-label, Phase Ib/II efficacy, and safety study of Berubicin utilizing a Simon’s 2-stage design to confirm the efficacy (or futility) of a single arm of Berubicin treatment, administered at the recommended Phase II dose (RP2D) identified in the Phase I study (7.5 mg/m² Berubicin HCl), on the endpoint of Overall Response Rate in up to approximately 61 patients with GBM. The trials will include an interim analysis of the first 18 patients in the first half of 2022 for efficacy and safety as well as an extensive pharmacokinetic profile for these patients.

More details about study could be found on ClinicalTrials.gov under number [NCT04915404](https://www.clinicaltrials.gov/ct2/show/NCT04915404). After approval of the study by the Regulatory Agency clinical sites data will also be available.

<https://www.clinicaltrials.gov/ct2/show/NCT04915404?term=wpd&draw=2&rank=3>

Phase I Pediatric Clinical Trial for Malignant Gliomas

WPD is planning the Phase I clinical trial for malignant gliomas at two clinical sites in Poland. The study includes a multicenter, open-label, dose escalation Phase I study of intravenous Berubicin in pediatric patients. The purpose of this first-in-pediatrics study is to examine the safety, tolerability, and pharmacokinetics of Berubicin and to estimate its MTD and/or RP2D when administered to pediatric patients with progressive, refractory, or recurrent HGG who have completed at least 1 standard line of therapy. This study will also make a preliminary assessment of the antitumor activity of Berubicin in this patient population in up to approximately 35 patients. This Phase I trial of Berubicin represents the first ever investigation of Berubicin in pediatric brain tumors.

WPD has already received Ethical Committee approval for Phase I clinical trial and has submitted its request for approval from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Information on approval and study number in European clinical trials database will be provided within 60 days. WPD expects to commence the Phase I clinical trial in Q3/Q4 2021.

CNS Commences Patient Enrollment in Potentially Pivotal Study of Berubicin

CNS Pharmaceuticals (NASDAQ:CNSP) (“**CNS**”), the company that sublicenses the compound Berubicin to WPD for 30 countries mainly in Europe and Asia, announced open enrollment in the United States for its clinical study evaluating the efficacy and safety of Berubicin in the treatment of recurrent GBM.

CNS’s potentially pivotal trial is an adaptive, multicenter, open-label, randomized and controlled study in adult patients with recurrent glioblastoma multiforme (WHO Grade IV) after failure of standard first-line therapy. The primary endpoint of the study is Overall Survival. Overall Survival is a rigorous endpoint that the U.S. Food and Drug Administration (FDA) has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm. Results from the trial will compare Berubicin to the current standard of care, with a 2 to 1 randomization of patients to receive either Berubicin or Lomustine.

Mariusz Olejniczak, CEO of WPD commented, “*I am very pleased and excited about the development we have made on Berubicin both in the United States and in Europe. Our combined WPD and CNS clinical studies are going to start to recruit patients shortly which is an exciting step in the development programs. To ensure patients are informed and updated on possible sites, we will use [clinicaltrials.gov](https://www.clinicaltrials.gov) as the primary source of information. We are hopeful that this is the first step in changing the landscape of glioma treatment with products in our pipeline and through collaboration with different companies,*

scientific institutions, and our license partners. I would like to take an opportunity to thank both the WPD and CNS teams and our vendors and partners including WWCT and IAG for the hard work during pandemic months.”

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. Berubicin, was developed by Dr. Waldemar Priebe, Professor of Medicinal Chemistry at The University of Texas MD Anderson Cancer Center.

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 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 for most compounds 30 countries in Europe and Asia, including Russia.

On Behalf of the Board

‘Mariusz Olejniczak’

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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 anticipates will or may occur in the future. Forward-looking statements in this press release include that WPD’s drugs could be developed into novel treatments for cancer, and that we anticipate starting the Phase II Trial of Berubicin in the second half of 2021 and will include an interim analysis of the first 18 patients in the first half of 2022; and we expect to commence the Phase I pediatric clinical trial in Q3/Q4 2021. These forward-looking statements reflect the Company’s current expectations based on information currently available to management and are subject to several 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 the technology may not provide the benefits expected and we may not engage them further; competitors or others may successfully challenge a granted patent and the patent 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; our expected timing of trials may be delayed; 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. The Company assumes no obligation to update them except as required by applicable law.