May 19, 2021

CNS Pharmaceuticals Commences Patient Enrollment in Potentially Pivotal Study of Berubicin

Study to evaluate efficacy and safety of Berubicin in the treatment of adult recurrent Glioblastoma Multiforme (GBM), one of the most aggressive types of brain cancer

Interim analysis of trial when 50% of planned subjects reach 6 months in study

Sublicensee, WPD Pharmaceuticals to initiate a Phase 2 multicenter clinical trial in Poland of Berubicin in GBM in the second half of 2021; Interim analysis of the first 18 adult patients expected in first half of 2022

HOUSTON, May 19, 2021 /PRNewswire/ --**CNS Pharmaceuticals, Inc.** (NASDAQ: CNSP) ("CNS" or the "Company"), a biopharmaceutical company specializing in the development of novel treatments for primary and metastatic cancers in the brain and central nervous system, today announced open enrollment for its potentially pivotal study evaluating the efficacy and safety of Berubicin in the treatment of recurrent GBM.

CNS' lead product candidate, Berubicin, is a novel anthracycline and the first anthracycline to cross the blood-brain barrier. It is in development for the treatment of a number of serious brain and CNS oncology indications. The Company intends to enroll approximately 210 subjects across 35 clinical sites in the U.S. and also plans to expand the trial into western Europe. For more information about the potentially pivotal Berubicin trial, visit

clinicaltrials.gov and reference identifier NCT04762069.

"We are delighted to begin patient enrollment and screening in this potentially pivotal trial that will provide greater insight into the potential of Berubicin to improve patient outcomes in the treatment of GBM. This represents an important milestone for our pivotal program," commented John Climaco, CEO of CNS Pharmaceuticals. "I would like to thank our clinical team for their commitment and drive to advance this important development program."

"There remains a critical unmet need in the treatment landscape for glioblastoma. The data seen to date from Berubicin is encouraging as a potential treatment option in this devastating disease. With patient enrollment now underway and dosing to commence soon hereafter, we are another step closer to providing patients with hope and a treatment that offers improvement in progression and, importantly, overall survival," added Erin Dunbar, MD, founding physician of the Brain Tumor Center and Director of Neuro-Oncology at Piedmont Atlanta Hospital, and Principle Investigator for the study.

The 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.

A pre-planned, non-binding futility analysis will be performed after approximately 30 to 50% of all planned patients have completed the primary endpoint at 6 months. This review will include additional evaluation of safety as well as secondary efficacy endpoints. Enrollment will not be paused during this interim analysis.

In addition to the Company's global trial, sublicensee partner in Poland, WPD Pharmaceuticals, will initiate a Phase 2 multicenter clinical trial of Berubicin in adult GBM in the second half of 2021 as well as a Phase 1 multicenter clinical trial of Berubicin in pediatric gliomas in 2021. The WPD trial in adults with GBM 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.

The FDA has granted CNS Pharmaceuticals Orphan Drug Designation for Berubicin, which provides seven years of marketing exclusivity upon approval of an NDA. CNS Pharmaceuticals intends to file for additional patents relating to Berubicin to further secure intellectual property protections.

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 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. During 2021, 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 (with extensive PK) 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.

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