September 30, 2021

CNS Pharmaceuticals Doses First Group of Patients with Berubicin, an FDA-Designated Fast Track Drug Candidate, in the Potentially Pivotal Study for the Treatment of Glioblastoma Multiforme (GBM)

Company continues to drive further patient enrollment with 9 clinical trial sites initiated to-date, and an additional 60 sites selected across the U.S., Italy, France, Spain, and Switzerland expected to initiate imminently

Compelling data of previously conducted studies for Berubicin enables advanced development toward potentially bringing a GBM therapy to market where there still remains a significant unmet need

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

HOUSTON, Sept. 30, 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 the dosing of the first patients in its Berubicin clinical development program for the treatment of recurrent glioblastoma multiforme (GBM), one of the most aggressive types of brain cancer. Further patient enrollment, randomization and dosing is currently underway as well as a robust lineup of clinical sites located globally which are advancing toward activation and enrollment.

"As one of the most aggressive, deadly and treatment-resistant cancers that forms in the brain where current standard of care remains ineffective in ~60% of patients, the treatment landscape for GBM is in desperate need of a better treatment option. We continue to be encouraged by the data seen from Berubicin to date and are excited to now have patient dosing underway in this potentially pivotal trial. Our team is committed to expeditiously advancing the study and look forward to further understanding the full potential of Berubicin to offer improvement and overall survival in this devastating disease," stated Erin Dunbar, M.D., founding physician of the Brain Tumor Center and Director of Neuro-Oncology at Piedmont Atlanta Hospital, and Principal Investigator for the study.

Berubicin is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier currently being evaluated in a global potentially pivotal study evaluating its efficacy and safety. 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. Approximately 243 patients with GBM after failure of standard first line therapy will be randomized in a 2:1 ratio to receive Berubicin or lomustine for the evaluation of Overall Survival, the primary endpoint of the study. 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.

In the Phase 1 clinical trial previously conducted evaluating Berubicin in patients with previously treated disease, 44% of the patients showed clinical benefit (49% of the Avastin-naïve patient population), with the demonstration that it was effective based on this patient population with a dismal median survival rate of only 14.6 months from diagnosis. One patient in the Phase 1 study had a durable Complete Response (CR, a demonstrated lack of detectable cancer cells) that has continued for 14 years, and another patient had a durable partial response, with others showing substantial stabilization of disease. Additionally, the novel anthracycline agent Berubicin appears to have a toxicity profile consistent with that of other anthracyclines and demonstrates activity as monotherapy for recurrent glioblastoma multiforme. Berubicin has side effects that are able to be effectively treated and managed.

"I am extremely pleased with the progress made to-date in this potentially pivotal trial. Our team has been working intensely to open sites in the U.S. and in Europe, understanding where we can best advance this important study. With hundreds of potentially competing GBM trials currently enrolling patients, the fact that we've been able to bring these initial sites on-line and get patients enrolled and dosed not only supports our strategic evaluation and selection, but also allows our data demonstrating Berubicin's potential effectiveness to

continue to convince the medical community that we have a new drug with impressive potential. With the de-risked profile of Berubicin, its mechanism of action, history of development, encouraging Phase 1 data, and safety in study design, I am personally more optimistic about our work than at any time since joining the Company," commented John Climaco, CEO of CNS Pharmaceuticals.

"The investigator dedication to advance the science and development of Berubicin we're seeing here is meaningful to these patients that are out of options. Berubicin provides an innovative option for treatment in GBM as a safe and potentially effective therapy. We look forward to providing data at the interim analysis of the study," added Sandra L. Silberman, M.D., Ph.D. Chief Medical Officer of CNS Pharmaceuticals.

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.

The FDA recently granted CNS Pharmaceuticals Fast Track Designation for Berubicin which enables more frequent interactions with the FDA to expedite the development and review process. As previously announced, the Company also received Orphan Drug Designation from the FDA which may provide seven years of marketing exclusivity upon approval of an NDA. Taken together the Company believes these important designations can be seen as a recognition of the significance of not only the unmet clinical need in GBM, but of our Berubicin program.

For more information about the potentially pivotal Berubicin trial, visitclinicaltrials.gov and reference identifier NCT04762069.

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 a clinical-stage pharmaceutical company developing a pipeline of anti-cancer drug candidates for the treatment of primary and metastatic cancers of the brain and central nervous system. The Company's lead drug candidate, Berubicin, is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier. Berubicin is currently in development for the treatment of a number of serious brain and CNS oncology indications including glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer.

Additionally, the Company is advancing the development of its WP1244 drug technology, which utilizes anthracycline and distamycin-based scaffolds to create small molecule agents and is believed to be 500x more potent than daunorubicin in inhibiting tumor cell proliferation. Preclinical studies of WP1244 demonstrated high uptake in the brain with antitumor activity. CNS Pharmaceuticals is evaluating the use of WP1244 in the treatment of brain cancers, pancreatic, ovarian, and lymphomas.

For more information, please visit www.CNSPharma.com, and connect with the Company on Twitter, Facebook, and LinkedIn.

Forward-Looking Statements

Some of the statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability of the Company's cash runway to extend until Q2 2022 and the timing of patient dosing to commence. These statements relate to future events, future expectations, plans and prospects. Although CNS believes the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. CNS has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including those discussed under Item 1A. "Risk Factors" in CNS's most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in its Form 10-Q filings and in its other public filings with the SEC. Any forward-looking statements contained in this press release speak only as of its date. CNS undertakes no obligation to update any forward-looking statements contained in this press release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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