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CNS Pharmaceuticals Announces Activation of First Clinical Trial Sites in Europe for Ongoing Potentially Pivotal Global Trial Evaluating Berubicin for the Treatment of GBM

Sites in France and Spain now open and actively enrolling

*Enrollment progressing with 26 clinical trial sites open to-date of the 59 sites
selected across the U.S., Italy, France, Spain, and Switzerland*

Interim analysis of the trial when 30-50% of subjects reach 6 months in study

HOUSTON, Sept. 28, 2022 /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 activation of its first clinical trial sites in Europe for the ongoing potentially pivotal global trial evaluating Berubicin for the treatment of recurrent glioblastoma multiforme (GBM), one of the most aggressive types of brain cancer. These first European clinical trial sites in France and Spain are now open and actively enrolling patients.



"Our primary focus continues to be on advancing the clinical development of Berubicin as a potential treatment option for this devastating disease. Over the course of this year, we have worked diligently to expand patient eligibility for our potentially pivotal trial and bolster our international presence now realized with the activation of the first two European clinical trial sites. This is a true testament to our team's commitment to and the execution of this important clinical program. We are grateful for the tremendous support from the clinical staff

and remain dedicated to driving patient enrollment as quickly and efficiently as possible. We look forward to continuing to build momentum and bringing Berubicin across the finish line to unlock its greatest potential. As long as the unmet medical need in GBM remains, we will continue our fight in earnest to bring hope to patients and families globally," commented John Climaco, CEO of CNS Pharmaceuticals.

Berubicin, is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier. Berubicin is currently being evaluated in a potentially pivotal global study evaluating its efficacy and safety in the treatment of GBM. The potentially pivotal trial is an adaptive, multicenter, open-label, randomized and controlled study in adult patients with recurrent glioblastoma multiforme (WHO Grade IV1) after failure of standard first-line therapy. The primary endpoint of the study is Overall Survival (OS), which is a rigorous endpoint that the 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 a current standard of care (Lomustine), with a 2 to 1 randomization of patients to receive either Berubicin or Lomustine. The recently amended protocol expands eligibility for the study to patients who have received additional treatments as part of the first line therapy for their disease considering advancements in this area. This change was made due to the complexity of new agents introduced as a component of first line therapy, which allows an additional group of patients that can enroll on the study after what may constitute multiple procedures as their initial treatment.

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 has granted CNS Pharmaceuticals Fast Track Designation for Berubicin which enables more frequent interactions with them to provide guidance on expediting the development and review process. Additionally, the Company has also received Orphan Drug Designation from the FDA which may provide seven years of marketing exclusivity upon approval of an NDA.

For more information about the potentially pivotal Berubicin trial, visit clinicaltrials.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 portfolio, 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 timing of enrollment of new patients and the ability of the Company to complete the trial on a timely basis, if at all. 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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