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CNS Pharmaceuticals Receives Approval from France Ethics Committee and Competent Authority for Potentially Pivotal Study of Berubicin for the Treatment of Glioblastoma Multiforme (GBM)

Company continues to drive global patient enrollment in pivotal study of Berubicin

HOUSTON, April 6, 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 it has received approval from the National Agency for the Safety of Medicine and Health Products (ANSM) Competent Authority and from the People Protection Ethics Committee (EC) SUD-EST III (CPP Sud-Est III) in France for the Company's potentially pivotal study of Berubicin for the treatment of recurrent glioblastoma multiforme (GBM), one of the most aggressive types of brain cancer.

"Access to patients is the lifeblood of any clinical study and this approval, in the second most populous country in Europe, provides just that for our Berubicin trial. We have said time and again that our number one priority is the advancement of this potentially pivotal study. This is evidenced by our continuous dedication to driving enrollment and bringing global clinical sites on line. We are grateful to the French Competent Authority and Ethics Committee and their positive feedback on what we believe is an incredibly important clinical program. Across the globe there is an urgent need for GBM treatment options. We will continue to press on in our efforts to advance Berubicin through the clinic and importantly, to patients and their families. I am proud of the progress our team has made to-date and believe there are additional clinical sites to join those that have already been added to this globlal potentially

pivotal study," commented John Climaco, CEO of CNS Pharmaceuticals.

Dr. Carole Gourmelon, MD, Institut de Cancérologie de l'Ouest, St Herblain, added, "GBM is a devastating disease with significant unmet need. I have been encouraged by the data Berubicin has demonstrated to date and look forward to further evaluating its potential to provide benefit to patients. Now with the necessary approvals received, I look forward to joining the Company's efforts to progress Berubicin through the clinic."

Berubicin is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier currently being evaluated in a potentially pivotal global study evaluating its efficacy and safety in the treatment of GBM. The potentially pivotal global 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.

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.

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 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 ability of the Company's cash runway to extend until Q1 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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