April 5, 2022

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

Company previously received approval from swissethics, the umbrella organization of the cantonal Ethics Committees (EC) in Switzerland for the study

Execution of global patient enrollment continues to progress in pivotal study of Berubicin for the treatment of GBM, one of the most aggressive forms of brain cancer

HOUSTON, April 5, 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 Swissmedic, the Swiss Agency for Therapeutic Products, for the Company's potentially pivotal study of Berubicin for the treatment of recurrent glioblastoma multiforme (GBM). With approvals now received from both swissethics, the umbrella organization of the cantonal Ethics Committees (EC) in Switzerland, and Swissmedic, the Company can proceed with site initiation and patient enrollment in Switzerland.

"With the necessary regulatory approvals in Switzerland now in place, our team is diligently working to bring clinical sites online and quickly and efficiently drive patient enrollment in this potentially pivotal study. We are sincerely grateful to the Swiss Competent Authority and Ethics Committee and their positive feedback on what we continue to believe is an incredibly important clinical program. We are laser focused on advancing Berubicin to unlock its

greatest potential as a possible critical treatment option for this devastating disease. As long as the unmet medical need in GBM remains, we will continue our fight to bring hope to patients and families," commented John Climaco, CEO of CNS Pharmaceuticals.

Professor Michael Weller, MD, University Hospital Zurich and National Coordinating Investigator for the potentially pivotal study, added, "The data Berubicin has shown to-date demonstrates encouraging promise in treatment of GBM. Patients and families are desperate for a viable treatment option that provides benefit and I look forward to further exploring Berubicin's potential. I am excited to be able to participate in this important clinical trial and join forces with CNS Pharmaceuticals in their effort to provide what could be an important, and crucial, treatment option."

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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