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FDA Grants Fast Track Designation to CNS Pharmaceuticals for Berubicin for the Treatment of Recurrent Glioblastoma Multiforme

- FDA Fast Track Designation for Berubicin highlights the serious unmet medical need for new treatments for glioblastoma multiforme (GBM)

- Company recently commenced enrollment in potentially pivotal study evaluating Berubicin in the treatment of adult recurrent glioblastoma multiforme

HOUSTON, June 29, 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 that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for its lead investigational drug, Berubicin, for the treatment of patients with recurrent glioblastoma multiforme (GBM). As previously reported, the Company has also received Orphan Drug Designation from the FDA for Berubicin for the treatment of patients with recurrent GBM.

"Receiving Fast Track Designation from the U.S. FDA is a huge achievement in our advancement of Berubicin for the treatment of glioblastoma, the most aggressive, deadly and treatment-resistant type of cancer that forms in the brain. If there were ever a disease where the unmet clinical need demands action, it is GBM. Patients have almost no meaningful options and thousands lose their fight against this terrible cancer every year. With this designation, we now have an accelerated pathway to approval for Berubicin

and a clear opportunity to more expediently bring this potentially impactful investigational therapy to individuals battling this challenging disease," commented John Climaco, CEO of CNS Pharmaceuticals.

Fast Track Designation enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

CNS recently announced the start of patient enrollment in its potentially pivotal study of Berubicin for the treatment of recurrent glioblastoma multiforme. For more information about this study, please 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, 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.

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