December 2, 2021

CNS Pharmaceuticals Receives Approval from Switzerland Ethics Committee for its Potentially Pivotal Study of Berubicin for the Treatment of Glioblastoma Multiforme (GBM)

Approval is the first from a European Ethics Committee for the potentially pivotal study of Berubicin with additional sites selected across the U.S., Italy, France, and Spain, expected to initiate imminently

HOUSTON, Dec. 2, 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 it has received approval from swissethics, the umbrella organization of the cantonal Ethics Committees (EC) in Switzerland, 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.

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.

"Receiving approval from swissethics is a significant milestone for the Company. Our stated goal is, and always has been, to see Berubicin approved for the treatment of glioblastoma, and this means globally. This terrible disease does not discriminate on the basis of geography or anything else: Patients in Europe are as desperate as patients in the United

States, and treating patients is not only why we do what we do, but how we do it as well. Driving patient enrollment is how we advance Berubicin's development and opening additional clinical sites around the globe is the pivotal piece that allows us to ramp up our efforts and move toward data. We are deeply grateful that Switzerland has the first European EC to approve our Berubicin trial, but we are confident it will be far from the last in this truly global effort. We have a number of additional clinical sites selected around the world that we anticipate coming online in the very near term. As we progress, my belief grows in the enormous potential of Berubicin to be a critical treatment option for this devastating disease. I am proud of the accomplishments we've made with this potentially pivotal trial to-date, but we will not pause for a single second until Berubicin reaches its full potential to offer hope to GBM patients everywhere," commented John Climaco, CEO of CNS Pharmaceuticals.

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, 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.

View original content to download multimedia:https://www.prnewswire.com/news-releases/cns-pharmaceuticals-receives-approval-from-switzerland-ethics-committee-for-its-potentially-pivotal-study-of-berubicin-for-the-treatment-of-glioblastoma-multiforme-gbm-301435822.html

SOURCE CNS Pharmaceuticals, Inc.