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CNS Pharmaceuticals Announces FDA Filing of IND for its Brain Cancer Drug Berubicin

Expects to initiate Phase 2 trial during the first quarter of 2021

HOUSTON, Nov. 17, 2020 /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 of the brain and central nervous system, today announced that it has submitted an Investigational New Drug (IND) application, which has been accepted for review, to the U.S. Food and Drug Administration (FDA) for Berubicin in the treatment of Glioblastoma Multiforme (GBM). The Company plans to evaluate the efficacy of Berubicin in a Phase 2 Trial for adults with GBM who have failed first-line therapy and commence the trial within the first quarter of 2021, pending the FDA's acceptance of the Company's filing.



"Our laser focus from the beginning has been to start the next phase of the investigation of Berubicin for the treatment of this deadly disease as quickly as possible," commented John Climaco, CEO of CNS Pharmaceuticals. "Our team has worked tirelessly for the past year, making several inroads on our manufacturing and clinical efforts to achieve this important milestone. We believe we are optimally positioned to continue to execute our plan and initiate our Phase 2 trial in the first quarter of 2021. We continue to build on the positive results Berubicin demonstrated in the Phase 1 study in high grade gliomas and look forward to advancing its clinical development in these patients, with the end goal of addressing the unmet medical need of better treatment for patients diagnosed with GBM."

The planned Phase 2 trial will evaluate the efficacy of Berubicin in patients with GBM who have failed primary treatment for their disease, and results will be compared to the current standard of care, with 2 to 1 randomization of the 243 patients to Berubicin or Lomustine.

The trial will include an interim analysis that will evaluate the comparative effectiveness of these treatments. The trial's adaptive design is intended to allow this interim analysis of the data to demonstrate meaningful differences in efficacy between treatments and then to allow an adjustment to the size of the patient population in the trial for maximum efficiency in terms of time in development. Based on this, the trial has the potential to provide data to the FDA that may allow an expedited pathway for development. However, there can be no assurance that the FDA will support any potential request for an expedited pathway to approval or further development.

About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals is developing novel treatments for primary and metastatic cancers of the brain and central nervous system. Its lead drug candidate, Berubicin, is proposed for the treatment of glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer. CNS holds a worldwide exclusive license to the Berubicin chemical compound and has acquired all data and know-how from Reata Pharmaceuticals, Inc. related to a completed Phase 1 clinical trial with Berubicin in malignant brain tumors, which Reata conducted in 2006. In this trial the overall response rate of stable disease or better was 44%. This 44% disease control rate was based on 11 patients (out of 25 evaluable patients) with stable disease, plus responders. One patient experienced a durable complete response and remains cancer-free as of Feb. 20, 2020. These Phase 1 results represent a limited patient sample size and, while promising, are not a guarantee that similar results will be achieved in subsequent trials. By the end of 2020, CNS expects to commence a Phase 2 clinical trial of Berubicin for the treatment of GBM in the U.S., while a sub-licensee partner undertakes a Phase 2 trial in adults and a first-ever Phase 1 trial in pediatric GBM patients in Poland. Its second drug candidate, WP1244, is a novel DNA binding agent that has shown in preclinical studies that it is 500 times more potent than the chemotherapeutic agent daunorubicin in inhibiting tumor cell proliferation.

For more information, please visit www.CNSPharma.com.

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 to seek accelerated approval from the FDA of a New Drug Application (NDA) following the planned Berubicin trial. 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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