October 29, 2020

CNS Pharmaceuticals Completes Manufacturing of Berubicin for Phase 2 Clinical Trial

CNS' lead drug candidate Berubicin is proposed for the treatment of glioblastoma multiforme ("GBM"), an aggressive form of brain cancer

HOUSTON, Oct. 29, 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 announces that its European manufacturer, BSP Pharmaceuticals S.p.A. ("BSP"), has completed the manufacturing process for Berubicin Drug Product, its lead drug candidate for the treatment of glioblastoma multiforme (GBM), an aggressive form of brain cancer currently considered incurable. With the completion of manufacturing at BSP and at its U.S. manufacturer, Pharmaceutics International, Inc. ("Pii"), the Company remains poised to file an Investigational New Drug Application ("IND") and initiate its Phase 2 U.S. clinical trial for Berubicin on its anticipated timeline.

"We are pleased to continue to execute upon our dual-track drug product manufacturing strategy, as both our U.S. manufacturer, Pii, and European manufacturer, BSP, have now completed production of Berubicin Drug Product," commented John Climaco, CEO of CNS Pharmaceuticals. "The completion of the manufacturing process at both locations represents a key milestone for us and will further support our efforts to file an IND during the fourth quarter of this year. We are encouraged by our continued execution upon our pre-trial initiatives, and believe we remain positioned to initiate a U.S. Phase 2 trial for Berubicin during the first quarter of 2021."

As previously announced, the Company implemented its dual-track drug product manufacturing strategy for Berubicin. As a part of its strategy, the Company engaged a U.S.

based manufacturer, Pii, and European manufacturer BSP, for the production of Berubicin Drug Product. The Company engaged two separate manufacturers in two separate continents in order to help mitigate COVID-19-related delay risks, diversify its supply chain and provide for localized availability of Berubicin. Both Pii and BSP have now completed the manufacturing process for Berubicin.

As the Company focuses on its IND filing preparations, it has made several key advancements on the clinical front to supplement its manufacturing efforts. The Company recently engaged Worldwide Clinical Trials as the contract research organization, Image Analysis Group ("IAG") as the imaging partner, and Berry Consultants as a biostatistical advisor for its Phase 2 trial design. Furthermore, the Company also bolstered its leadership team in advance of the trial and appointed Dr. Patrick Wen, a renowned neuro-oncologist, to its Scientific Advisory Board. The FDA granted the Company Orphan Drug Designation (ODD) for Berubicin for the treatment of malignant gliomas, which include GBM. The designation provides Berubicin with certain benefits during the product's development to treat malignant gliomas and provides CNS with the potential for market exclusivity upon the drug's approval for that use.

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, 44% of patients experienced a statistically significant improvement in clinical benefit. 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 file an IND in the fourth quarter of this year and to initiate its Phase 2 trial for Berubicin in the first quarter of 2021. 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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