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CNS Pharmaceuticals Announces US Drug Manufacturing Milestones

HOUSTON, Sept. 3, 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 central nervous system, today provides an update on progress for the U.S. manufacturing of Berubicin, the Company's lead drug candidate, in preparation for upcoming clinical trials.

As previously announced, the Company implemented a dual-track drug product manufacturing strategy and engaged U.S.-based Pharmaceutics International, Inc. ("Pii") and Italy-based BSP Pharmaceuticals S.p.A. ("BSP") for the production of Berubicin. By engaging two separate manufacturers on two separate continents, CNS expects to mitigate COVID-19-related delay risks, diversify its supply chain and provide for localized availability of Berubicin.

Under this dual-track strategy, the Company has achieved several key milestones in its manufacturing efforts and is providing an update on the progress made with its U.S. manufacturer, Pii. First, CNS completed synthesis of Berubicin active pharmaceutical ingredient (API) and shipped API to both manufacturers to prepare an injectable form of Berubicin for clinical use. In preparation for production, CNS and Pii have now agreed on the manufacturing procedure and packaging components for Berubicin and selected a sterile filter manufacturer. The Company has also completed and reviewed a draft of the batch record. Importantly, the Company and Pii completed a successful laboratory simulation of the lyophilization cycle. The Company expects to begin manufacturing of Berubicin at Pii during the third quarter of this year.

"As we prepare to initiate our upcoming Berubicin clinical trials, our execution both on the clinical and manufacturing fronts remain paramount to our success," stated John Climaco, CEO of CNS Pharmaceuticals. "We continue to be encouraged as our partner Pii has now

delivered upon many of the critical steps necessary to ensure the quality and availability of Berubicin. We look forward to keeping you updated on our progress as we continue our preparations to submit an IND for Berubicin during the fourth quarter of this year."

CNS's preparations for filing an IND entail both extensive clinical and manufacturing initiatives. In addition to the progress the Company has made in its manufacturing efforts, it has recently announced critical achievements made on the clinical front. The Company engaged Worldwide Clinical Trials ("Worldwide") as the contract research organization (CRO) for its upcoming Berubicin clinical trials. Worldwide specializes in therapeutic areas with unmet medical needs, including CNS disorders and oncology. Worldwide will work closely with CNS to provide proactive insight and operational support for its upcoming trials. Additionally, the Company engaged Berry Consultants, a leading clinical statistical consulting group, to advise on its Phase 2 trial design for Berubicin. Berry Consultants uses Bayesian statistics to provide innovative clinical trial designs and analysis. The Company has also completed the Phase 1 Clinical Study Report, or CSR, which is now ready for publication.

CNS was recently granted Orphan Drug Designation (ODD) for its lead product, Berubicin, for the treatment of malignant gliomas. The designation provides Berubicin with a special status that can help accelerate its development to treat malignant gliomas by providing CNS with the potential for market exclusivity upon the drug's approval. The Company plans to file an IND for Berubicin with the FDA during the fourth quarter of 2020.

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 February 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.

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 initiate its Phase 2 trial by the end of 2020. 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 in the Company's SEC filings, including under Item 1A "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our 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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