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CNS Pharmaceuticals Begins Manufacturing of Berubicin in Europe

HOUSTON, Oct. 9, 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 the Company's European manufacturer, BSP Pharmaceuticals S.p.A. ("BSP"), has begun 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.

"Our preparations for filing an IND for Berubicin require continued execution in both our clinical and manufacturing initiatives," stated John Climaco, CEO of CNS Pharmaceuticals. "With the manufacturing of our Berubicin Drug Product in Europe, we continue to advance closer toward an IND filing for Berubicin, which we expect to submit later this quarter. We have also made significant progress on the clinical front and 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 our Phase 2 trial design. We have also added Dr. Patrick Wen, a renowned neuro-oncologist, to our Scientific Advisory Board. Our laser focus remains on initiating a U.S. Phase 2 trial for Berubicin in Q1 of 2021 and we continue to demonstrate our ability to execute our operational and clinical plans toward that goal."

As part of the Company's plan to mitigate COVID-19-related delay risks, diversify its supply chain and provide for localized availability of Berubicin, the Company implemented a dual-track drug product manufacturing strategy. Under this dual-track strategy, it engaged two separate manufacturers for Berubicin on different continents, both U.S.-based Pharmaceutics International, Inc. ("Pii") and Italy-based BSP. As previously announced, CNS completed synthesis of Berubicin active pharmaceutical ingredient (API) and shipped API to both Pii and BSP to prepare an injectable form of Berubicin for clinical use. BSP and

Pii have now begun manufacturing of Berubicin and the Company expects to complete manufacturing at both locations early in the fourth quarter.

The FDA recently 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 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 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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