

August 25, 2020



## CNS Provides FDA Update on IND Filing

### Berubicin Previously Received FDA Orphan Drug Designation

HOUSTON, Aug. 25, 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 provided an update on the Company's plans for its lead product candidate, Berubicin, which is being studied for the treatment of glioblastoma multiforme (GBM). The company has taken significant strides in designing Phase 2 clinical trials and anticipates submitting an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) this year and initiating clinical trials in early 2021. In preparing for the IND submission, CNS has focused on clinical trial design and implementation, as well as establishing the necessary manufacturing capabilities.



On the clinical front, the Company has engaged Worldwide Clinical Trials (Worldwide) as the contract research organization (CRO) that will be conducting the upcoming Berubicin clinical trials. Worldwide, which specializes in therapeutic areas with unmet medical needs, including CNS disorders and oncology, will work closely with CNS to provide proactive insight and operational support. . In addition, the Company has engaged Berry Consultants, a leading clinical statistical consulting group, to advise on the Phase 2 trial design. Berry Consultants utilizes Bayesian statistics to provide innovative clinical trial designs and analysis. In preparation for submitting the IND, CNS also has completed the Clinical Study Report, or CSR, for a Phase 1 study for which the Company holds the rights.

CNS also has made several key advances in drug manufacturing, with the goal of ensuring the quality and availability of Berubicin for the upcoming clinical trials. As part of a dual track product manufacturing strategy, CNS has engaged US-based Pharmaceuticals International, Inc., (Pii) and Italy-based BSP Pharmaceuticals S.p.A., (BSP) to produce the Berubicin finished drug product. CNS believes this strategy will help mitigate COVID-19 related risks, diversify the Company's supply chain, and provide for localized availability of Berubicin. The

Company completed synthesis of Berubicin active pharmaceutical ingredient (API) and shipped API to both manufacturers to prepare an injectable form of Berubicin for clinical use.

"We are extremely encouraged by the consistent progress we have made in preparation for our upcoming Berubicin clinical trials," commented John Climaco, CEO of CNS Pharmaceuticals. "The CNS team is deeply experienced in the design and execution of clinical trials and as a result of our preparations, we have continued to deliver upon our strategic timeline and remain on track to execute our upcoming milestones. We believe our efforts optimally position us to submit an IND for Berubicin in the fourth quarter of this year." Unless FDA acts to the contrary, an IND goes into effect 30 calendar days after submission to the agency, which allows the sponsor to initiate the clinical trial presented in the IND.

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. 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 GBM trial in adults and a first-ever Phase 1 trial in pediatric GBM patients in Poland. The Company's second drug candidate, WP1244, is a novel DNA binding agent that in preclinical studies has shown promising potency 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 for Berubicin during the fourth quarter 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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