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CNS Pharmaceuticals Engages CRO For Phase 2 Berubicin Clinical Trials

Selects Worldwide Clinical Trials as Contract Research Organization Partner

HOUSTON, Aug. 20, 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 it has engaged [Worldwide Clinical Trials](#) ("Worldwide") as the contract research organization ("CRO") for its upcoming Berubicin clinical trials.



Worldwide is a full-service, midsize, global CRO that provides drug development services to biopharmaceutical companies in clinical trials. Worldwide specializes in therapeutic areas where there remain unmet medical needs, including CNS disorders and oncology. Worldwide provides proactive insight and operational support and has successfully managed clinical trials across more than 60 countries.

"Designing and operating trials in areas of high unmet medical need, such as glioblastoma, is a challenging and complex task for any company. We are excited to bring on a high caliber partner such as Worldwide, which has extensive expertise in CNS and oncology, as our CRO for the upcoming Berubicin clinical trials," commented John Climaco, CEO of CNS Pharmaceuticals. "Engaging Worldwide is one of the key pieces of our preparations. We maintain that their insight and unparalleled experience in trials of this nature provide the best opportunity to further drive Berubicin's clinical development. We believe that with Worldwide's deep clinical CNS and oncology experience, and through our achievements in trial preparation, we are optimally positioned for our upcoming Phase II Berubicin trials in adults in the US and Poland as well as our Phase I pediatric trial."

"The relationship between CNS Pharmaceuticals and Worldwide exemplifies state-of-the-art

strategic program development – innovative program design coupled to exceptional clinical and operational acumen for a compound that offers considerable promise to both adults as well as children with such devastating illnesses," commented Michael F. Murphy, MD, PhD, Chief Medical and Scientific Officer at Worldwide. "Speaking on behalf of our organization, it is a privilege to express our personal and professional commitment to its success."

The Company's decision to engage Worldwide as its CRO for the upcoming Berubicin clinical trials is the latest milestone in a series of recent preparation achievements. The Company has been active in implementing its strategic plan and engaged US-based Pharmaceuticals International, Inc., (Pii) and Italy-based BSP Pharmaceuticals S.p.A., (BSP) for the production of Berubicin drug product. The decision to add both Pii and BSP as manufacturers of Berubicin was part of the Company's strategy to implement a dual-track drug product manufacturing strategy. The Company believes this dual-track strategy will help mitigate COVID-19 related risks, diversify its supply chain, and provide for localized availability of Berubicin. Furthermore, 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.

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 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.

About Worldwide Clinical Trials

Worldwide Clinical Trials employs more than 1,700 professionals around the world, with offices in North and South America, Eastern and Western Europe, Russia, and Asia. Founded by physicians committed to advancing medical science, Worldwide is out to change how the world experiences CROs—in the best possible way. From early phase and bioanalytical sciences through late phase, post-approval and real-world evidence, we provide world-class, full-service drug development services.

With infrastructure and talent spanning 60 countries, we execute predictable, successful studies with operational excellence across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, general medicine, oncology and rare diseases. We never compromise on science or safety. We're never satisfied with the status quo. We're the Cure for the Common CRO.

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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