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CNS Pharmaceuticals Reports Full Year 2022 Financial Results and Provides Corporate Update

Potentially pivotal Phase 2 trial of Berubicin for the treatment of recurrent glioblastoma multiforme (GBM) demonstrating rapid pace of enrollment globally

Company on track to report results of the pre-planned interim analysis in the third quarter of 2023

HOUSTON, TX / ACCESSWIRE / April 3, 2023 [CNS Pharmaceuticals, Inc.](#)

[\(NASDAQ:CNSP\)](#) ("CNS" or the "Company"), a biopharmaceutical company specializing in the development of novel treatments for primary and metastatic cancers in the brain and central nervous system, today reported its financial results for the full year ended December 31, 2022 and provided a clinical update of its anti-cancer drug candidate currently in development for the treatment of primary and metastatic brain and CNS cancer.

"Over the course of 2022, we made significant advancements in our ongoing clinical trial for Berubicin. We have expanded our clinical trial sites across Europe and continued with an encouraging and increasingly rapid pace of enrollment. As it currently stands, we are on track to reach our pre-planned interim analysis during the third quarter of 2023. We remain laser focused on moving this trial toward the finish line and importantly, potentially address the significant unmet need that currently exists for the treatment of GBM," commented John Climaco, CEO of CNS Pharmaceuticals. "We are incredibly grateful to all stakeholders including our clinical staff for the continued support and execution. We believe 2023 is poised to be the most important year for the Company to-date and we continue to focus on the operational execution that will deliver the potential value-driving milestones in the near term."

Berubicin Highlights

Ongoing potentially pivotal trial evaluating lead product candidate Berubicin for the treatment of recurrent glioblastoma multiforme (GBM)

The Company has opened 41 clinical trial sites of the 60 sites selected across the U.S., Italy, France, Spain, and Switzerland in its ongoing potentially pivotal study to evaluate efficacy of Berubicin in the treatment of adult GBM.

A pre-planned, non-binding interim futility analysis will be conducted by an independent Data Safety Monitoring Board (DSMB) to recommend whether this study should continue as planned based on Berubicin showing value as a second-line treatment for patients with

glioblastoma compared with Lomustine. The Company will conduct this analysis after at least 50% of the patients in the population to be analyzed for the interim analysis (30-50% of the total number of patients for this trial) can be evaluated as having failed the primary efficacy endpoint (death). The DSMB will review the number of deaths on each arm to ensure that the overall survival of patients receiving Berubicin shows at least a statistically significant comparability to those receiving Lomustine. The median survival of patients receiving second-line treatment for glioblastoma has historically been shown to be approximately 6 months. The Company has previously used this 6 months as an estimate for the time to a 50% mortality rate. Taking into account the recent rate of enrollment and the number of patients that can be adequately assessed for their follow-up outcomes, the Company is anticipating that the DSMB will be able to perform this interim analysis and the Company can release the data during the third quarter of 2023. Additional analyses that will be provided based on this data will be comparisons of secondary endpoints, including progression-free survival (PFS), response rates, and safety assessments. Enrollment will not be paused during this interim analysis.

Upcoming Milestones

- Interim analysis of the trial, expected during the third quarter of 2023;
- Complete enrollment in potentially pivotal clinical trial for GBM; and
- Report topline results.

The FDA has granted CNS Pharmaceuticals Fast Track Designation for Berubicin which enables more frequent interactions with them to provide guidance on expediting the development and review process. Additionally, the Company has received Orphan Drug Designation from the FDA which may provide seven years of marketing exclusivity upon approval of an NDA. For more information about the potentially pivotal Berubicin trial, visit clinicaltrials.gov and reference identifier NCT04762069.

Summary of Financial Results for the Full Year 2022

The net loss for the year ended December 31, 2022 was approximately \$15.3 million compared to approximately \$14.5 million for the comparable period in 2021. The change in net loss is primarily attributable to increased general and administrative costs.

The Company reported research and development expenses of \$9.3 million for the year ended December 31, 2022 compared to approximately \$9.8 million for the comparable period in 2021. The decrease in research and development expenses during the period were mainly attributed to the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year, and this lower level of manufacturing activity is expected to continue throughout this year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in contract research organization (CRO) expenses related to continued progress with our Phase II clinical trial.

General and administrative expense was approximately \$6.0 million for the year ended December 31, 2022 compared to approximately \$4.7 million for the comparable period in 2021. This change is primarily attributable to an increase of approximately \$1.1 million in professional expenses, \$315,000 in employee compensation, \$334,000 related to the write

off of deferred offering costs and \$84,000 in other general and administrative expenses. These changes were offset by decreases of \$502,000 in stock-based compensation and advertising and marketing of \$41,000.

As of December 31, 2022, the Company had cash of approximately \$10.1 million and working capital of approximately \$7.6 million. The Company's current expectation is that the cash on hand and the proceeds from the \$6.0 million offering completed in November 2022 is sufficient to fund our operations into, but not beyond, the third quarter of 2023. The timing and costs of clinical trials are difficult to predict and trial plans may change in response to evolving circumstances and as such the foregoing estimates may prove to be inaccurate.

About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals a clinical-stage pharmaceutical company developing a pipeline of anti-cancer drug candidates for the treatment of primary and metastatic cancers of the brain and central nervous system. The Company's lead drug candidate, Berubicin, is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier. Berubicin is currently in development for the treatment of a number of serious brain and CNS oncology indications including glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer.

For more information, please visit www.CNSPharma.com, and connect with the Company on [Twitter](#), [Facebook](#), and [LinkedIn](#).

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 Company's timing of the interim analysis to occur in the third quarter of 2023, and the ability to continue to open additional clinical trial sites on a timely basis. 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.

CONTACTS:

Investor Relations Contact

JTC Team, LLC
Jenene Thomas
833-475-8247
CNSP@jtcir.com

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