May 14, 2021

# CNS Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Business Outlook

## Company poised to transition to late-stage clinical company with launch of potentially pivotal study evaluating efficacy of Berubicin in the treatment of adult Glioblastoma Multiforme (GBM) this quarter

## Potentially pivotal GBM study derisked with interim analysis when 50% of planned subjects reach 6 months in study

## Platform opportunities for expansion into additional oncology indications with significant unmet needs

## Company well-positioned to execute on multiple value-driving milestones over the course of 2021

HOUSTON, May 14, 2021 /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 (CNS), today reported its financial results for the quarter ended March 31, 2021. Additionally, the Company provided a clinical update as well as a business outlook.

"2021 is poised to be an exciting year for the Company. Throughout the first quarter, we have made continued development and regulatory progress on all fronts and are committed to driving our novel treatments forward as expeditiously as possible with the primary focus on our Berubicin program to improve patient outcomes for GBM," commented John Climaco,

CEO of CNS Pharmaceuticals. "We are looking forward to the near-term initiation of patient enrollment in our potentially pivotal trial, which we believe will be a catalytic event in the evolution of CNS Pharmaceuticals as it transitions us into a late-stage clinical company. We look forward to gaining additional insight into Berubicin's potential to unlock powerful benefits in the fight against GBM which remains as one of the most aggressive types of brain cancer. We believe there is significant potential to unlock shareholder value over the course of the next 18 months and we look forward to providing continued updates and driving momentum."

**Clinical Programs Update**

*Berubicin – Novel anthracycline*

CNS' lead product 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. The Company expects to commence patient enrollment in its potentially pivotal study evaluating the efficacy of Berubicin in the treatment of adult GBM in the second quarter. For more information about the potentially pivotal Berubicin trial, visit clinicaltrials.gov and reference identifier NCT04762069.

In addition to the Company's global trial, sublicensee partner in Poland, WPD Pharmaceuticals, will initiate a Phase 2 multicenter clinical trial of Berubicin in GBM in the second half of 2021 and report an interim analysis of the first 18 patients by Q1-Q2 2022.

**Anticipated Upcoming Milestones:**

- Commence patient enrollment in potentially pivotal study to evaluate efficacy of Berubicin in the treatment of adult GBM in Q2 2021;
- WPD Pharmaceuticals to initiate a Phase 2 multicenter clinical trial of Berubicin in GBM in the second half of 2021;
- The WPD trial interim analysis of the first 18 patients by Q1-Q2 2022 for efficacy as well as an extensive pharmacokinetic profile in these patients;
- CNS Pharmaceuticals to report interim analysis of U.S. adult GMB trial when 50% of planned subjects reach 6 months in study;
- WPD will commence a multicenter Phase 1 pediatric trial for malignant CNS tumors in 2021;
- CNS will conduct pre-clinical evaluation of Berubicin for additional CNS cancers and cancers metastatic to the brain, including development of potential combination therapies for these indications; and
- CNS Pharmaceuticals to expand pipeline in the evaluation of other drugs for brain cancers.

The FDA has granted CNS Pharmaceuticals Orphan Drug Designation for Berubicin, which provides seven years of marketing exclusivity upon approval of an NDA. CNS Pharmaceuticals intends to file for additional patents relating to Berubicin to further secure intellectual property protections.

*WP1244 Portfolio - Novel class of DNA-binding agents*

The Company continues to advance the development of its WP1244 drug technology, which utilizes anthracycline and distamycin-based scaffolds to create small molecule agents and is believed to be 500x more potent than daunorubicin in inhibiting tumor cell proliferation. Preclinical studies of WP1244 demonstrated high uptake in the brain with antitumor activity. CNS Pharmaceuticals is evaluating the use of WP1244 in the treatment of brain cancers, pancreatic, ovarian, and lymphomas.

**Anticipated Upcoming Milestones**

- File IND in 2022

**Summary of Financial Results for First Quarter 2021**

The net loss for the three months ended March 31, 2021 was approximately $3.6 million compared to approximately $2.0 million for the comparable period in 2020. The change in net loss is attributable to increased personnel and activity associated with preparing for the Company's clinical trials in 2020. The Company reported Research and development expenses of $2.2 million for the three months ended March 31, 2021 compared to approximately $0.6 million for the comparable period in 2020. The expenses incurred during the period were related to drug manufacturing and labor related to the preparation of our Phase 2 study. General and administrative expense was approximately $1.4 million for the three months ended March 31, 2021 compared to approximately $1.3 million for the comparable period in 2020. The Company ended the quarter with $11.0 cash and cash equivalents, expected to fund operations into 2022.

**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 the overall response rate of stable disease or better was 44%. 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 Feb. 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. During 2021, 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 (with extensive PK) 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.

For more information, please visit www.CNSPharma.com.

View original content to download multimedia:http://www.prnewswire.com/news-releases/cns-pharmaceuticals-reports-first-quarter-2021-financial-results-and-provides-business-outlook-301291412.html

SOURCE CNS Pharmaceuticals, Inc.