April 23, 2020

CNS Pharmaceuticals Announces Filing of FDA Orphan Drug Designation for Brain Cancer Drug Berubicin

HOUSTON, April 23, 2020 /PRNewswire/ -- CNS Pharmaceuticals, Inc. (NASDAQ: CNSP) ("CNS" or the "Company"), a biotechnology company specializing in the development of novel treatments for brain tumors, today announced it has filed an application with the U.S. Food and Drug Administration (FDA) to receive Orphan Drug Designation (ODD) for its lead product Berubicin.

Under a prior developer, Berubicin, then known as RTA 744, was granted ODD by the FDA for the treatment of malignant gliomas. In the prior developer's Phase 1 trial of Berubicin, 44% of the patients demonstrated a significant improvement in progression free survival. Additionally, one patient in this study experienced a complete response to his treatment with Berubicin.

"We are excited to announce the Orphan Drug application submission for Berubicin, as it would grant special status and accelerate the development of Berubicin to treat glioblastoma, one of the world's most aggressive forms of cancer," stated John Climaco, CEO of CNS Pharmaceuticals. "We are pleased to continue to execute upon our strategic initiatives and submit our application within the anticipated timeline outlined within our previous filings. We feel cautiously optimistic about the application, given the past Orphan Drug Designation of the molecule and positive Phase 1 results. We look forward to initiating a Phase II trial evaluating the effect of Berubicin on patients with glioblastoma later this year."

The Orphan Drug Act ("ODA") provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status").

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Due to small patient numbers, treatment for these rare diseases would not be considered economically feasible without government programs to support their economic viability. Orphan Drug Designation would qualify Berubicin for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees. The receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval.

About Berubicin
Berubicin is an anthracycline, a class of anticancer agents that are among the most powerful chemotherapy drugs and effective against more types of cancer than any other class of chemotherapeutic agents. Anthracyclines are designed to utilize natural processes to induce deoxyribonucleic acid (DNA) damage in targeted cancer cells by interfering with the action of topoisomerase II, a critical enzyme enabling cell proliferation. Berubicin treatment of brain cancer patients appeared to demonstrate positive responses that include one durable complete response in a Phase 1 human clinical trial conducted by Reata.

About CNS Pharmaceuticals, Inc.
CNS Pharmaceuticals is a biotechnology company specializing in the development of novel treatments for primary and metastatic brain and central nervous system tumors. Its lead candidate Berubicin is proposed for the treatment of glioblastoma, a type of brain cancer currently considered incurable, as well as for pancreatic and ovarian cancers, and lymphomas. The Company entered into an intellectual property (IP) agreement with Houston Pharmaceuticals, Inc. and a Purchase Agreement with Reata. For more information, visit www.cnspharma.com.

Forward-Looking Statements
Some of the statements in this 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 receive orphan drug designation for Berubicin and to commence Phase II trials of Berubicin this year. These statements relate to future events, future expectations, plans and prospects. Although CNS believes that 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 in our 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 release speak only as of its date. CNS undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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