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CNS Pharmaceuticals Completes Pilot Manufacturing Steps Pursuant to FDA Pre-IND Guidance

HOUSTON, Jan. 28, 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 that Anthem Biosciences of Bangalore, India (Anthem) has completed a pilot run of the recrystallization of the Reata Pharmaceuticals, Inc. API (Reata). It has also completed a lyophilization of the API. Samples of the drug product, which include 299 capped vials, have been shipped to Intertek Pharmaceutical Services (Intertek) for further analysis and release.

As previously announced, the FDA agreed in a preclinical submission that CNS could use Reata API as long as it was reprocessed and released under GMP conditions, and that the new lyophilized form of the drug product could be used during the Company's upcoming clinical trial. Anthem, a full-service provider of GMP manufacturing for APIs, completed this pilot run of the Reata API. The pilot run recrystallization passed all specifications at Intertek. The recrystallized API was shipped to Lyophilization Technology, Inc. a leader of GMP lyophilization of Drug Products for clinical trials, which completed a pilot lyophilization. The pilot run of lyophilized API was successfully tested and released by Intertek. DavosPharma, a Davos Chemical Company, acted on behalf of the Company as the coordinating manufacturing broker for all of these processes.

"We are excited to achieve another important milestone in the development of Berubicin," stated John Climaco, CEO of CNS Pharmaceuticals. "We look forward to completing both GMP manufacturing processes and release for clinical trials."

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 a COA for the GMP reprocessed API, and to achieve the large-scale production of Berubicin. 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 the heading "Risk Factors" in the Form S-1 we filed with the SEC on October 7, 2019. 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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