

CNS Pharmaceuticals Completes Active Ingredient Shipments to Manufacturers

HOUSTON, July 8, 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, announced today it has completed shipping its Active Pharma Ingredient (API) to both Maryland based Pharmaceutics International, Inc., (Pii) and Italian BSP Pharmaceuticals S.p.A., (BSP), respectively, for the production of Berubicin.



"As we continue to prepare for our upcoming Berubicin Phase 2 trial, ensuring proper manufacturing and delivery of drug product is a key priority," stated John Climaco, CEO of CNS Pharmaceuticals. "We are excited to execute on yet another key milestone, and deliver Berubicin's API to our trusted partners PII and BSP. We will continue our focus on executing upon all of the necessary steps as we look to pave the way for our upcoming U.S. Phase 2 trial, expected to initiate during the fourth quarter of this year."

CNS previously entered into manufacturing contracts with Pii and BSP for the production of Berubicin, its lead drug candidate for the treatment of glioma brain tumors. The decision to implement a binary manufacturing strategy mitigates COVID-19 related manufacturing risks for the upcoming Phase I study in Poland and the upcoming U.S. Phase 2 trial. The first API shipments to PII and BSP commenced in June.

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 trial with Berubicin in GBM which Reata conducted in 2006. In this trial,

44% of patients experienced a statistically significant improvement in progression-free survival. 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. In the second half 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.

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 in the fourth quarter of this year. 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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