February 21, 2023

Processa Pharmaceuticals

Processa Pharmaceuticals Announces Prioritization on Development of Next Generation Chemotherapies

- **Our Next Generation Chemotherapies (NGCs) are cancer treatments where the metabolism and/or distribution of an FDA-approved drug has been altered to provide potentially safer and more effective chemotherapy to cancer patients.**
- **Based on preliminary clinical and pre-clinical studies, more cancer patients should benefit from our NGCs than their FDA-approved counterpart drugs.**
- **Our Regulatory Science approach, encompassing the principles of FDA's Project Optimus and Oncology Guidance, should increase the likelihood of approval.**
- **FDA meetings are planned in 2023 to discuss the next phases of development and our plan to include the principles of Project Optimus and the Oncology Guidance.**
- **Opportunities to monetize or partner non-oncology assets are being evaluated.**

HANOVER, MD, Feb. 21, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company") reiterates the strategic prioritization of its pipeline of proprietary oncology drugs, defined as Next Generation Chemotherapies (NGCs). Previous studies with these NGCs suggest potential improvement in the safety-efficacy profile will significantly differentiate these NGCs from their three presently widely used counterparts - capecitabine, gemcitabine, and irinotecan.

Much of oncology research and drug development focuses on the search for a new or different way to treat cancer. Processa's approach is to modify and improve three different, widely used chemotherapy treatments with a proven history of successfully treating many cancer patients but also having a high rate of non-responders and a significant number of patients who must decrease the dose or discontinue treatment because of adverse events. The NGCs have been modified using a proprietary approach such that they are metabolized and/or distributed differently in the body than their approved counterpart drugs, while still maintaining the same mechanism of killing the cancer cells.

Dr. David Young, Processa's President and CEO stated, "The Company's Next Generation Chemotherapy treatments have the potential to extend the survival and/or quality of life for more cancer patients than their existing counterpart drugs while decreasing the number of patients who are required to dose adjust or discontinue treatment because of adverse events. Based Processa's Regulatory Science approach which incorporates the principles associated with FDA's Project Optimus Oncology Guidance, we have already begun to evaluate the safety-efficacy profiles including the dose-adverse event and dose-efficacy response relationship. By being able to understand these dose-response relationships, we should be able to better select dosage regimens of each Next Generation Chemotherapy treatment that will provide a better safety-efficacy profile than their widely used marketed counterpart drugs. Following this approach will not only increase the likelihood of obtaining

FDA approval, but also provide the evidence that our Next Generation Chemotherapies are safer and more efficacious than the existing treatments."

Each of the Company's pipeline of three NGC treatments is briefly described:

(1) NGC-Capecitabine is a combination of PCS6422 and capecitabine. PCS6422 alters the metabolism of capecitabine without having any clinically meaningful biological effect itself. In clinical trials, NGC-Capecitabine has been shown to be greater than fifty times more potent with an improved safety profile over capecitabine. Like capecitabine, NGC-Capecitabine could be used to treat patients with cancers, such as metastatic colorectal, gastrointestinal, breast, and pancreatic. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with metastatic colorectal, gastrointestinal, breast, and pancreatic cancers. We plan to meet with the FDA in the first half of 2023 to discuss the Phase 2B design, including the implementation of the FDA Project Optimus Oncology initiative and the recent Oncology Guidance as part of the design. We are planning to initiate a Phase 2B trial in the second half of 2023 subject to funding.

(2) NGC-Gemcitabine (PCS3117) is an oral analog of gemcitabine that is converted to its active metabolite by a different enzyme system than gemcitabine resulting in a positive response in gemcitabine patients as well as some gemcitabine treatment-resistant patients. Like gemcitabine, NGC-Gemcitabine could be used to treat patients with cancers such as pancreatic, lung, ovarian, and breast. We estimate at least 275,000 patients in the United States were diagnosed in 2022 with pancreatic, lung, ovarian, and breast cancer. We plan to meet with the FDA in 2023 to discuss potential study designs, including the implementation of the FDA's Project Optimus Oncology initiative and the recent Oncology Guidance as part of the design. The Phase 2B protocol will be submitted to the existing IND in the second half of 2023 with the initiation of the trial, subject to funding requirements, occurring soon after the submission to the IND.

(3) NGC-Irinotecan (PCS11T) is a prodrug of the active metabolite of irinotecan (SN-38). The chemical structure of PCS11T influences the uptake of NGC-Irinotecan into cancer cells resulting in more NGC-Irinotecan entering cancer cells than normal cells in mice. These levels were significantly greater than those seen with irinotecan, resulting in lower doses of NGC-Irinotecan having greater efficacy than Irinotecan and improved safety in animal models. Like irinotecan, NGC-Irinotecan could be used to treat patients with cancers such as lung, colorectal, gastrointestinal, and pancreatic cancer. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with lung, colorectal, gastrointestinal, and pancreatic cancer. We plan to conduct IND enabling and toxicology studies in 2023 and 2024, subject to funding.

Consistent with the shift in priority, including the allocation of resources to these NGC drugs, the Company has begun and will continue to meet with potential licensing partners, as well as pursue other options to monetize PCS12852 and PCS499.

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses its Regulatory Science Approach

criteria when selecting and developing drugs to achieve high-value milestones effectively and efficiently. Processa will prioritize the three Next Generation Chemotherapy oncology treatment programs: Next Generation Capecitabine (PCS6422 and Capecitabine to treat metastatic colorectal, gastrointestinal, breast, pancreatic, and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

For more information, visit our website at www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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