March 17, 2023

Processa Pharmaceuticals Announces First Patient Dosed in the 300 mg Dose Group with Next Generation Chemotherapy-Capecitabine

- **The 300 mg dose group will provide more information on the drug exposure vs adverse event relationship which is critical to FDA approval given the FDA's Project Optimus Oncology initiative.**
- **Patients treated with Next Generation Chemotherapy-Capecitabine have NOT had hand-foot syndrome or cardiotoxicity adverse events, typically seen in 50-70% of patients presently on FDA-approved capecitabine.**
- **In mid-April Processa expects guidance from FDA on our Phase 2B trial design and our Project Optimus approach.**

HANOVER, MD, March 17, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a developer of Next Generation Chemotherapies (NGCs), today announced that the Company has dosed the first patient in its NGC-Capecitabine (combination of PCS6422 and capecitabine) 300 mg dose group. The Processa NGCs already have clinical evidence to support their safety and efficacy while they target patients who need better treatment options for their cancer in order to improve survival and/or quality of life.

"We are pleased to have now dosed the first patient in our 300 mg dose group. This dose group will provide more information on the drug exposure vs adverse event relationship which is critical to FDA approval given FDA's Project Optimus Oncology initiative. In addition, the data obtained from this dose group will help us to better understand how PCS6422 alters capecitabine metabolism to form more cancer-killing metabolites and fewer metabolites that only cause dose-limiting side effects," said Dr. David Young, President and CEO of Processa.

Dr. Young added, "We anticipate completion of enrollment in the Phase 1B trial in mid-2023 and are excited to have high exposure of the cancer-killing metabolites without the hand-foot syndrome or cardiotoxicity side effects that typically occur in 50-70% of the patients presently treated with FDA-approved capecitabine. Further, we expect our discussions on our Phase 2B trial with FDA in mid-April to enhance our collaboration with the FDA on their Project Optimus Oncology initiative for all our NGCs while clearing the way to both finalize our Phase 2B protocol and to initiate the trial in the 2nd half of this year."

The Company will hold its year-end 2022 earnings call on March 30, 2023.

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop the Next Generation Chemotherapies (with existing

clinical evidence of safety and efficacy) for cancer patients who need better cancer drugs to extend survival and/or improve their quality of life. The Company uses its Regulatory Science Approach and the principles of the FDA's Project Optimus Oncology initiative to provide an efficient development program, increase the probability of approval, and provide a safer and better cancer treatment that can be easily differentiated from what is presently on the market and in development. Processa is developing three Next Generation Chemotherapy oncology treatments: 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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Source: Processa Pharmaceuticals, Inc.