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Processa Pharmaceuticals

Processa Pharmaceuticals to Conduct Next Generation Chemotherapy-Capecitabine Phase 2 Trial Based on FDA Guidance and Project Optimus Oncology Initiative

HANOVER, MD, May 18, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company") today announces it has received guidance from the U.S. Food and Drug Administration ("FDA") regarding the Company's next trial for Next Generation Chemotherapy-Capecitabine ("NGC-Cap"). The trial for NGC-Cap, the combination of PCS6422 and capecitabine, will be a Phase 2 safety-efficacy trial in colorectal cancer patients following the principles of FDA's Project Optimus Oncology Initiative, the recent FDA recommendation on how oncology drugs are to be developed going forward.

David Young, Pharm.D., Ph.D., Processa's President and CEO, commented, "Our communications with the FDA have been extremely productive. One of the most important advantages of NGC-Cap and all our NGC drugs is that they have been designed to decrease the side effects associated with the treatment while increasing the exposure of cancer cells to proven cancer-killing molecules. These changes are expected to increase the number of patients who will benefit from each NGC drug given fewer side effects as well as have a significant impact on a patient's response.

"By combining our NGCs and the Processa Regulatory Science Approach with FDA's Project Optimus, Processa can efficiently provide better therapeutic options to cancer patients while increasing the likelihood of successful marketing approval. In addition, prior to approval, we expect to show that there are significant advantages to treating patients with our NGC drugs over both existing chemotherapy and oncology drugs directed toward new targets or new mechanisms. We look forward to continued collaboration with FDA and to providing continued updates to our shareholders," concluded Dr. Young.

The Phase 2 trial will be designed to determine the dose-and exposure-response relationships for both anti-tumor activity and safety/tolerability by evaluating different dosage regimens. The final dosage regimens to be used in the Phase 2 trial will be defined following the determination of the maximum tolerated dose from the Company's ongoing Phase 1b trial and in collaboration with the FDA. To expedite the enrollment of the first patient, Processa has begun the upfront study preparation tasks, including protocol preparation for submission to the existing IND and clinical enrollment planning.

About Processa Pharmaceuticals, Inc.

Processa is a clinical stage pharmaceutical company focused on developing Next

Generation Chemotherapy (NGC) drugs intended to improve the safety, tolerability, and efficacy of cancer treatment. Some of the key advantages of Processa's NGCs are expected to be fewer patients experiencing side effects that lead to dose discontinuation, more significant cancer response, and an increase in the number of patients who will benefit from each NGC drug. The NGC drugs are modifications of existing FDA-approved oncology drugs resulting in an alteration of the metabolism and/or distribution of these FDA-approved drugs while maintaining the existing mechanisms of killing the cancer cells. By combining the proven cancer-killing active molecules and the Processa Regulatory Science Approach with FDA's new Project Optimus Oncology Initiative, Processa can provide better therapeutic options to cancer patients more efficiently while increasing the probability of FDA approval. Using its Regulatory Science Approach, the Processa team has consistently demonstrated its ability to obtain FDA approvals as evidenced by over 30 approvals for indications across almost every division of the FDA. Our pipeline includes 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, biliary duct, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

For more information, please visit our website atwww.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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