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Processa Pharmaceuticals Announces Successful Phase 2 Meeting with FDA for Next Generation Capecitabine

FDA provides guidance on Phase 2 design and Processa to continue with pre-study activities for Phase 2 trial

HANOVER, MD, Dec. 13, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical-stage pharmaceutical company focused on developing the next generation of chemotherapeutic drugs to improve the efficacy and safety for more patients suffering from cancer, announces the outcomes from a successful meeting with the U.S. Food and Drug Administration ("FDA") regarding the Company's next Phase 2 study supporting the advancement of Next Generation Capecitabine ("NGC-Cap") for cancer patients.

"The FDA provided helpful guidance on the overall design of our NGC-Cap Phase 2 study for which we anticipate beginning enrollment in mid-2024. We believe that NGC-Cap may provide a better safety/efficacy profile than FDA-approved Capecitabine, eventually providing treatment for the tens of thousands of patients who cannot tolerate the existing Capecitabine," said David Young, PharmD, Ph.D, President of Research and Development at Processa. "The results to date of our present Phase 1b oncology study clearly show that the metabolism and distribution of NGC-Cap is better than Capecitabine and that the safety/efficacy profile will likely be significantly better once we can identify the optimal dosage regimen."

The FDA provided guidance on the study design, the protocol, and the determination of the optimal dosage regimen using the principles of Project Optimus. The meeting with the FDA was supported by the interim results from the ongoing Phase 1b study that should complete enrollment in the first quarter of 2024. These interim results are expected to be available for public release by the end of the year.

About Capecitabine Administered with PCS6422 (NGC-Cap)

NGC-Cap combines the administration of PCS6422, the Company's irreversible dihydropyrimidine dehydrogenase (DPD) enzyme inhibitor, with the administration of low doses of the commonly used chemotherapy Capecitabine.

Capecitabine is the oral form of 5-FU and, along with 5-FU, is among the most widely used chemotherapy drugs available, particularly for solid tumors. When metabolized (after oral ingestion), it becomes 5-FU in the body, which, in turn, metabolizes to molecules called anabolites that actively kill duplicating cells, such as cancer cells, and to molecules called catabolites that only cause side effects. The presence of the DPD enzyme plays an integral role in the undesirable conversion of 5-FU to catabolites.

PCS6422 is a uracil analog that irreversibly inhibits DPD. PCS6422 is neither toxic nor active as a single agent in animals at comparable dose levels. However, when administered in combination with Capecitabine or 5-FU, PCS6422 decreases the metabolism of 5-FU to the catabolites that only cause side effects.

About Processa Pharmaceuticals, Inc.

Processa is a clinical stage pharmaceutical company focused on developing the Next Generation Chemotherapy (NGC) drugs to improve the safety and efficacy of cancer treatment. By combining Processa's novel oncology pipeline with proven cancer-killing active molecules and the Processa Regulatory Science Approach as well as experience in defining Optimal Dosage Regimens for FDA approvals, Processa not only will be providing better therapy options to cancer patients but also increase the probability of FDA approval for its Next Generation Chemotherapy (NGC) drugs following an efficient path to approval. Processa's 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. The company's approach to drug development is based on more than 30 years of drug development expertise to efficiently design and conduct clinical trials that demonstrate a positive benefit/risk relationship. The Processa team has a track record of obtaining over 30 approvals for indications across almost every division of FDA. Using its proven Regulatory Science Approach, the Processa Team has experience defining the Optimal Dosage Regimen using the principles of the FDA's Project Optimus Oncology initiative. The advantages of Processa's NGCs are expected to include fewer patients experiencing side effects that lead to dose discontinuation, more significant cancer response and a greater number of patients -- in excess of 200,000 for each NGC drug -- who will benefit from each NGC drug. Currently under development are 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 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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