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Processa Pharmaceuticals

Processa Pharmaceuticals Provides Data Update Supporting a Potential Personalized Treatment Approach for Improved Cancer Care

Interim analysis of Phase 1B data suggests Processa's novel chemotherapy treatment could improve safety and efficacy in more patients by individualizing the dosing regimen for each patient

HANOVER, MD, Aug. 17, 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 patients suffering from cancer, provides an interim analysis from its ongoing Phase 1B trial of Next Generation Capecitabine (NGC-Cap) in patients with gastrointestinal cancer, which identifies a personalized treatment approach that may yield improved safety and treatment efficacy. NGC-Cap combines the administration of PCS6422, Processa's irreversible dihydropyrimidine dehydrogenase (DPD) enzyme inhibitor, with low doses of the commonly used chemotherapy capecitabine, which is metabolized to 5-fluorouracil (5-FU) in the body. DPD promotes the further metabolism of 5-FU to fluor-beta-alanine (FBAL), a metabolite that leads to dose-limiting chemotherapy side effects.

Processa has found that regularly measuring the concentrations of DPD, as expressed by the metabolite FBAL, may provide a method to better understand how each patient responds to different NGC-Cap dosage regimens. This insight potentially allows physicians to develop and administer patient-specific treatment protocols of NGC-Cap for each patient to inhibit the development of side effects and promote broader drug efficacy, patient safety, and tolerability.

Currently, capecitabine, among the most widely used chemotherapy drugs, is dosed based on a standard dosage regimen for all patients. Unfortunately, many patients cannot tolerate that dose and must either have their dose reduced or have their treatment interrupted. These modifications are often associated with reduced efficacy in treating cancer.

Sian Bigora, Pharm.D., Processa's Chief Development and Regulatory Officer, commented, "The presence of DPD as expressed by the plasma concentration of FBAL provides us important information that may confirm our hypothesis that we can optimize our dosing of NGC-Cap to maintain efficacy and minimize side effects by carefully tracking each individual patient following an initial dosing of our novel chemotherapy. By following the chemical concentration in the plasma in each patient, we may be able to actually optimize therapy through individualization of each patient's dosing regimen. We find these results, albeit early results, to be very encouraging."

In the ongoing Phase 1B study, Processa followed the activity of DPD following NGC-Cap

dosing by measuring 5-FU and FBAL in the plasma of patients. FBAL has *no cancer-killing* activity but is known to *cause dose-limiting side effects* such as Hand-Foot Syndrome. The data shows that DPD enzyme activity (as represented by FBAL levels) was extremely low for approximately 24-48 hours in patients who received PCS6422 plus capecitabine. The low level of the DPD enzyme activity during the first 24-48 hours resulted in capecitabine being metabolized mainly to its active cancer-killing metabolites instead of FBAL. Over the next 3-6 days, the amount of FBAL increased and the levels of 5-FU decreased as a result of the increased DPD activity due to newly formed DPD enzyme (de novo synthesis). This leads to the progressive reduction of the cancer-killing metabolites and the anti-cancer activity of the therapy.

David Young, Pharm. D., Ph.D., Processa's President of R&D, added, "As we continue to obtain data from the Phase 1B trial, we are able to better understand the relationship between the concentrations of FBAL and 5-FU in the body relative to the time of administration and formation of de novo DPD. This study has already demonstrated that the addition of PCS6422 to low doses of capecitabine results in the formation of more cancer-killing metabolites before the concentration of the metabolites that only cause dose-limiting side effects significantly increases. Part of our ongoing objectives for the Phase 1B trial and our planned Phase 2 trial will be to determine the optimal regimen of NGC-Cap to balance the safety and efficacy profiles for each individual patient by monitoring DPD activity through 5-FU and FBAL. We look forward to continuing to investigate NGC-Cap and to providing updates as they develop."

The first three of five cohorts in the Phase 1B trial have completed enrollment and the initial safety evaluation. The fourth cohort has completed enrollment, and the safety evaluation is ongoing. Enrollment in the last cohort is expected to be completed in 4Q23, leading to an assessment of the safety profile and potentially preliminary efficacy of NGC-Capecitabine in totality across all cohorts by year-end. This cumulative view of the safety profile will allow Processa to determine the appropriate dose regimens to be used in its planned Phase 2 study in patients with colorectal cancer to determine the Optimal Dose Regimen, as mandated by the FDA's new Project Optimus Initiative.

About Next Generation Capecitabine (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.

PCS6422 is an uracil analog that irreversibly inhibits dihydropyrimidine dehydrogenase (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 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 drugs. Processa's NGC drugs are modifications of existing FDA-approved oncology drugs resulting in an alteration of the metabolism and/or distribution of drugs while maintaining the existing mechanisms of killing the cancer cells. Our 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. Using its proven Regulatory Science Approach, we have experience defining the Optimal Dosage Regimen using the principles of the FDA's Project Optimus Oncology initiative. The advantages of Processa's Next Generation Chemotherapy drugs are expected to include fewer patients experiencing side effects that lead to dose discontinuation; more significant cancer response; and a greater number of patients who will benefit from each Next Generation Chemotherapy drug. Currently in our pipeline are three Next Generation Chemotherapy drugs: 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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