

Processa Pharmaceuticals Presents Two Abstracts at the AACR Annual Meeting 2024 Including New Data on the NGC-Cap Phase 1b Trial

NGC-Cap demonstrated greater 5-FU exposure than monotherapy capecitabine at a significantly lower dose with a favorable clinical safety profile

NGC-Cap holds potential for improved efficacy in more patients due to an increase in distribution of 5-FU to cancer cells

Phase 1b study final results to be released upon database lock

HANOVER, Md., April 11, 2024 (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 with improved efficacy and safety, presented two abstracts at the American Association for Cancer Research (AACR) Annual Meeting 2024, including new Phase 1b data on its Next Generation Capecitabine (NGC-Cap) product. These abstracts are available in the [Publications](#) section of Processa's website.

The NGC-Cap Phase 1b trial evaluated ascending doses of capecitabine when combined with a fixed dose of PCS6422 in patients with advanced, relapsed, or refractory progressive gastrointestinal cancer. These patients had to relapse from or fail all other treatments. NGC-Cap demonstrated greater 5-FU (5-fluorouracil) exposure and lower fluoro-beta-alanine (FBAL) exposure with a better or similar side effect profile compared with monotherapy capecitabine.

"The most recent data for the Phase 1b NGC-Cap study presented at AACR highlight NGC-Cap's ability to distribute more 5-FU to cancer cells with 5-10 times greater systemic exposure than when capecitabine is administered alone. As expected with a higher systemic exposure, there was a greater incidence of adverse events with NGC-Cap. However, these adverse events were less dose limiting than seen with other 5-FU metabolites," stated David Young, PharmD, Ph.D., President of Research and Development at Processa. "This Phase 1b study is ongoing due to continued patient response and we plan to release final trial data once the database is locked. Given we have identified the recommended Phase 2 doses and the maximum tolerated dose, we look forward to advancing NGC-Cap into a Phase 2 trial in breast cancer later this year. As agreed to with the FDA, our data in past and ongoing studies will be used to support the breast cancer Phase 2 trial, which streamlines the regulatory path for NCG-Cap."

The poster presentation, titled "Next generation capecitabine (NGC-Cap) in Phase 1b trial significantly increases 5-FU exposure while improving safety profile compared to

capecitabine,” reported the following more recent findings:

- 18 patients were enrolled in the first four dose levels of capecitabine in NGC-Cap
- The 5-FU exposure, expressed as the area under the 5-FU plasma concentration curve or AUC (geometric mean, CV%), for the two highest doses cohorts of 150 and 225 mg twice-daily NGC-Cap were 4,551 (26.8%) and 6,889 (41.4%) ng-hr/ml, respectively, which is approximately 5-10 times the AUC (0-inf) of 698 (33%) previously reported for a larger dose of approximately 2,250 mg twice-daily of monotherapy capecitabine (Reigner 1998)
- Similarly, the 5-FU maximum plasma concentrations (C_{max}) for these two cohorts were greater at 1.5 times the C_{max} of monotherapy capecitabine
- As expected, with the greater 5-FU exposure for all the NGC-Cap cohorts, the incidence of anabolite related side effects was also greater than monotherapy treatment, suggesting that more drug was distributed to duplicating cancer cells and normal cells
- The extremely low FBAL catabolite formation and exposure across all NGC-Cap doses resulted in the incidence of catabolite related side effects to be less with only one patient having Grade 1 hand-foot-syndrome, an FBAL related side effect often requiring dose modifications

In addition, Processa presented a second abstract at AACR titled “Application of phase 1 and pre-clinical data to assist in determining the optimal dosage regimen for cancer drugs using the principles of Project Optimus.” This abstract briefly describes the U.S. Food and Drug Administration’s (FDA) Project Optimus Initiative and draft optimal dosage regimen (ODR) guidance, which requires an ODR justified by a dose-ranging efficacy and safety study, as opposed to a maximum tolerated dose approach. Processa provided preclinical and Phase 1 oncology study examples to demonstrate how the exposure-response relationships for safety and efficacy can provide the recommended dose range to define and justify the optimal dosage regimen in an efficacy-safety study, in a pivotal study, and for FDA approval. The abstract also noted that Project Optimus may require alterations to the design, analysis, and interpretation of clinical trials for cancer drugs compared with what has been done in the past.

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, particularly for the treatment of 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 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, allowing more of the 5-FU to distribute to cancer cells.

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 its 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 provide better therapy options to cancer patients, but will also increase the probability of FDA approval for its 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 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 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 the 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 NGC treatments: Next Generation Capecitabine (PCS6422 and capecitabine to treat breast, metastatic colorectal, gastrointestinal, pancreatic and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, biliary, 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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