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Processa Pharmaceuticals Provides Clinical Update on Phase 2 Study in Metastatic Breast Cancer

Preliminary Phase 2 data demonstrate PCS6422+Capecitabine increased cancer-killing metabolite exposure while maintaining comparable safety to monotherapy capecitabine

Company on track to conduct formal interim analysis in early 2026

VERO BEACH, Fla., Dec. 17, 2025 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical-stage biopharmaceutical company developing Next Generation Cancer (NGC) therapies, today provided a clinical update on its ongoing Phase 2 study of NGC-Cap, the combination treatment of PCS6422 and capecitabine, in patients with advanced or metastatic breast cancer.

Data from the first 16 of 19 patients enrolled indicate that NGC-Cap significantly increases exposure to capecitabine cancer-killing drug metabolites without increasing the severity of side effects compared to standard monotherapy capecitabine therapy (Mono-Cap). This profile suggests the potential for improved clinical efficacy while maintaining manageable safety, a key objective of Processa's NGC platform.

The full interim analysis from the first 20 patients enrolled in the study, which will include efficacy and safety data, is expected in early 2026.

"These emerging data continue to validate the central premise of our Next Generation Cancer strategy," said Dr. David Young, President of Research and Development at Processa. "NGC-Cap (capecitabine combined with PCS6422) appears to meaningfully increase exposure to the capecitabine metabolites responsible for killing cancer cells, while reducing exposure to the catabolite metabolites associated with dose-limiting toxicity such as hand-foot-syndrome (HFS), a profile that is difficult to achieve with conventional Mono-Cap dosing."

"As we approach our planned interim analysis, we believe NGC-Cap continues to demonstrate a differentiated pharmacologic profile that could meaningfully improve the therapeutic index of capecitabine-based therapy," said George Ng, Chief Executive Officer of Processa Pharmaceuticals. "We view this program as a key value driver for the Company and an important opportunity for patients with advanced or metastatic breast cancer."

Preliminary Phase 2 study findings suggest that NGC-Cap may allow patients to receive greater exposure to the most effective cancer-killing components of therapy while avoiding increased severity of side effects commonly associated with standard treatment. The Company believes this balance between potential efficacy and tolerability is central to improving outcomes in patients with advanced breast cancer.

Key Safety and Pharmacokinetic Observations

19 patients have been randomized to receive either NGC-Cap (150 mg twice daily) or a standard-dose Mono-Cap (1,000 mg/m² twice daily). The evaluation of safety data from the first 16 patients provides preliminary findings consistent with higher exposure to active cancer-killing metabolites in the NGC-Cap arm. The data from all 19 patients were not available for this preliminary analysis.

As expected with increased exposure to active metabolites, a greater proportion of patients receiving NGC-Cap experienced side effects related to these capecitabine cancer-killing metabolites, and the total number of such side effects per patient was higher compared to patients receiving capecitabine alone. Importantly, the severity of these side effects was similar between treatment arms, indicating that the increased activity did not translate into more severe toxicity.

In addition to forming active metabolites, capecitabine is also broken down into catabolite metabolites, including FBAL, which are associated with certain side effects such as HFS. Patients receiving NGC-Cap demonstrated substantially lower exposure to FBAL — up to ten times less than with Mono-Cap.

Consistent with this reduced exposure, the number of patients reporting HFS was similar between treatment groups, but patients in the NGC-Cap arm experienced only mild (Grade 1) symptoms, while patients receiving capecitabine monotherapy experienced symptoms of greater severity (up to Grade 2).

“What we are seeing in patients aligns closely with our pharmacologic expectations,” added Dr. Young. “The distribution and severity of observed side effects are consistent with enhanced exposure to active cancer-killing metabolites and reduced formation of catabolites, including FBAL.”

Upcoming Clinical Milestone

Processa anticipates completing enrollment of the final patient in the formal 20-patient interim analysis of Phase 2 safety and efficacy study by the end of the first quarter of 2026, in accordance with the trial protocol.

About PCS6422+Cap (NGC-Cap)

NGC-Cap is Processa’s lead oncology asset and a key component of its Next Generation Cancer (NGC) platform. When administered, NGC-Cap is designed to increase systemic exposure to active cancer-killing anabolite metabolites while reducing formation of toxic catabolite metabolites, potentially improving the therapeutic index of Capecitabine-based therapy.

About Processa Pharmaceuticals, Inc.

Processa is a clinical-stage pharmaceutical company focused on developing the Next Generation Cancer (NGC) drugs with improved safety and efficacy. Processa’s NGC drugs are modifications of existing FDA-approved oncology therapies resulting in an alteration of the metabolism and/or distribution of these drugs while maintaining the existing mechanisms of killing the cancer cells. By combining its novel oncology pipeline with proven cancer-killing

active molecules and its Regulatory Science Approach, Processa's strategy is to develop more effective therapy options with improved tolerability for cancer patients through an efficient regulatory path. In addition to its core oncology programs, Processa is actively pursuing strategic partnerships for non-oncology assets to unlock additional value.

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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