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Processa Pharmaceuticals

Processa Pharmaceuticals Completes Enrollment of 20th Patient for Formal Interim Analysis in Phase 2 NGC-Cap Breast Cancer Study

Interim safety and efficacy data to be reported in Q1

VERO BEACH, Fla., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical-stage biopharmaceutical company developing Next Generation Cancer (NGC) therapies, today reported that it completed the enrollment and dosing of the 20 patients required for the planned formal interim analysis in its ongoing Phase 2 clinical study evaluating NGC-Cap, Processa's proprietary combination treatment of PCS6422 and capecitabine, in patients with advanced or metastatic breast cancer.

"This is an important milestone because it allows us to assess whether NGC-Cap can demonstrate a meaningful improvement over capecitabine monotherapy in both safety and efficacy for patients who have already undergone multiple prior cancer treatments.," said George Ng, Chief Executive Officer of Processa Pharmaceuticals.

Study Design and Patient Characteristics

The randomized, FDA-recommended Phase 2 study is designed to compare NGC-Cap (Arm A) with standard-of-care capecitabine monotherapy (Mono-Cap, Arm C) in patients with advanced or metastatic breast cancer. Patients enrolled in the study were required to have received at least one prior cancer treatment, with a median of two to three prior treatment regimens across the enrolled population.

NGC-Cap consists of a single dose of PCS6422 administered one day prior to capecitabine, followed by capecitabine at 150 mg twice daily for seven days on treatment and seven days off. The Mono-Cap arm consists of capecitabine administered at 1,000 mg/m² twice daily for 14 days followed by seven days off treatment.

PCS6422 is designed to re-engineer capecitabine metabolism by increasing the formation of cancer-killing metabolites (anabolites) while decreasing the formation of metabolites associated primarily with side effects (catabolites).

Formal Interim Analysis Objectives

The formal interim analysis will compare safety and preliminary efficacy outcomes between the NGC-Cap and Mono-Cap treatment arms and is expected to be completed in the first quarter of 2026. Key objectives of the interim analysis include:

- Evaluating the comparative safety and efficacy of NGC-Cap versus Mono-Cap

- Determining whether a higher or lower dose of NGC-Cap should be added as a third study arm
- Assessing whether the overall sample size of the Phase 2 study should be adjusted based on interim findings

“The interim analysis is designed to evaluate early signals of clinical benefit and to guide potential optimization of dose selection and overall study design,” said Dr. David Young, President of Research and Development at Processa. “These data will be critical as we determine the most appropriate path forward to maximize the therapeutic potential of NGC-Cap.”

About NGC-Cap (PCS6422+Capecitabine)

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 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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