October 2, 2024

Processa Pharmaceuticals Announces First Patient Dosed in Phase 2 Clinical Trial of NGC-Cap in Metastatic Breast Cancer

- Phase 2 trial is an adaptive designed randomized study comparing NGC-Cap to monotherapy capecitabine
- Results from this Phase 2 trial will evaluate NGC-Cap's safety-efficacy profile and help to define the optimal dosage regimen in patients with metastatic breast cancer

HANOVER, Md., Oct. 02, 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, today announced that the first patient has been dosed in a Phase 2 clinical trial evaluating NGC-Cap for the treatment of advanced or metastatic breast cancer.

"Dosing the first patient in this Phase 2 trial is a significant step in the development of NGC-Cap as a more effective and better tolerated treatment than widely used capecitabine and 5-FU," stated David Young, PharmD, Ph.D., President of Research and Development at Processa. "We expect this Phase 2 trial to build upon NGC-Cap's positive Phase 1b findings and we look forward to announcing the results from our interim analysis of this Phase 2 trial in mid-2025."

The Phase 2 trial (NCT06568692) is a global multicenter, open-label, adaptive designed safety-efficacy trial comparing two different doses of NGC-Cap to FDA-approved monotherapy capecitabine in approximately 60 to 90 patients with advanced or metastatic breast cancer. The trial is designed to evaluate the safety-efficacy profile of NGC-Cap versus monotherapy capecitabine, to determine the potential optimal dosage regimens of NGC-Cap as required by the FDA Project Optimus Initiative and to evaluate the possibility of personalizing NGC-Cap therapy.

To date, three clinical trial sites, including some with multiple clinical locations, have received institutional review board approval to participate in this study and are recruiting patients. Processa plans to activate approximately 30 sites worldwide.

Breast cancer is the second most common cancer and a leading cause of cancer-related death. More than 2 million cases of breast cancer were diagnosed in 2022 with more than 665,000 deaths globally. The five-year survival rate for those diagnosed with metastatic breast cancer is approximately 30%.

About Capecitabine Administered with PCS6422 (NGC-Cap)

NGC-Cap combines the administration of PCS6422, the Company's irreversible

dihydropyrimidine dehydrogenase (DPD) enzyme inhibitor, with low doses of capecitabine. Capecitabine is the oral prodrug of 5-fluorouracil (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 causing side effects while simultaneously decreasing tumor exposure to 5-FU and its cancer-killing anabolites.

About Processa Pharmaceuticals, Inc.

Processa is a clinical-stage pharmaceutical company focused on developing the Next Generation Chemotherapy (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.

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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