July 30, 2024

Processa Pharmaceuticals

Processa Pharmaceuticals Announces FDA Clearance of IND Application for a Phase 2 Clinical Trial of NGC-Cap in Breast Cancer

Open-label Phase 2 trial in breast cancer to begin this quarter

Initial data expected mid-2025

HANOVER, Md., July 30, 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 U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for Next Generation Capecitabine (NGC-Cap), its lead product candidate. The IND supports the initiation of a Phase 2 clinical trial in patients with advanced or metastatic breast cancer, which is expected to begin enrollment this quarter.

"We are proud to achieve this significant milestone for NGC-Cap and look forward to entering the clinic for the treatment of advanced or metastatic breast cancer, where capecitabine is a standard of care. We previously demonstrated in our Phase 1b study that NGC-Cap is more potent than monotherapy capecitabine, providing up to 5-10 times more 5-fluorouracil exposure to cancer cells. This greater exposure resulted in a greater efficacy, with a safety profile better or similar to existing monotherapy with capecitabine," stated David Young, PharmD, Ph.D., President of Research and Development. "Initial data from the Phase 2 trial are expected mid-2025."

"Although capecitabine is among the most widely used chemotherapy drugs, particularly for the treatment of solid tumors, there remains the need for a more effective chemotherapy treatment with fewer or less-severe side effects," he added. "We believe that NGC-Cap can fulfill this need."

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 disease is approximately 30%.

The Phase 2 study will be a global multicenter, open-label, adaptive design 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. Processa expects to enroll the first patient into this trial in the third quarter of 2024.

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-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 while simultaneously decreasing tumor exposure to 5-FU and it's anabolites.

The NGC-Cap Phase 1b study evaluated ascending doses of capecitabine when combined with a fixed dose of PCS6422 in patients with advanced, relapsed or refractory progressive gastrointestinal tract cancer. These patients had to relapse from or fail all other treatments. NGC-Cap demonstrated greater 5-fluorouracil (5-FU) exposure and lower fluoro-beta-alanine (FBAL) exposure with a better or similar side effect profile compared with monotherapy capecitabine, as well as preliminary anti-tumor activity. In all evaluable patients who received one dose of PCS6422 and seven days of capecitabine, partial responses or stable disease was observed in 66.7% (8 out of 12) of patients with progression-free survival of approximately 5 to 11 months across these patients.

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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Source: Processa Pharmaceuticals, Inc.