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Processa Pharmaceuticals

Processa Pharmaceuticals Announces Positive Efficacy Results from Preliminary Evaluation of Phase 1b Dose-escalating Trial with NGC-Cap in Gastrointestinal Cancer

Eight of 12 evaluable patients (66.7%) had progression-free survival (PFS) rangingfrom 5 to 11 months

At the highest NGC-Cap dose, all three evaluable patients had PFS with two partial responses (PR) and one stable disease (SD)

For all NGC-Cap doses, 5-Fluorouracil (5-FU) exposure was greater and fluoro-beta-alanine (FBAL) exposure was lower with a better or similar side-effect profile than monotherapy capecitabine

HANOVER, MD., June 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, today announced positive efficacy results from the preliminary evaluation of its recently completed Phase 1b clinical trial which defined the Maximum Tolerated Dose (MTD) and Recommended Phase 2 Dose Range (RP2DR) for Next Generation Capecitabine (NGC-Cap) administered to patients with Stage III or IV gastrointestinal tract (GI) cancer.

“We are encouraged by the preliminary efficacy analysis from our NGC-Cap Phase 1b dose-escalating safety/tolerability trial demonstrating some anti-tumor activity in patients with advanced GI cancer who have progressive cancer after relapsing or not responding to prior therapy. The favorable response is likely due to NGC-Cap’s ability to distribute more 5-FU to cancer cells than monotherapy capecitabine. The promising Phase 1b safety and tolerability profile plus these early efficacy signals provide validation for further development of NGC-Cap,” stated David Young, PharmD, Ph.D., President of Research and Development at Processa. “From this Phase 1b trial, we have been able to define the MTD and the RP2DR to use in our Phase 2 Optimal Dosage Regimen trial in breast cancer in the third quarter of 2024.”

Dr. Young added, “Given the need for more effective chemotherapy treatment with improved tolerability across multiple types of cancer, we believe that NGC-Cap has the potential to provide a safer, more efficacious option to treat the different cancers for which capecitabine and 5-FU are presently used.”

The NGC-Cap Phase 1b trial is evaluating ascending doses of capecitabine when

administered after a single dose of PCS6422 in Stage III or IV patients with advanced, relapsed or refractory progressive GI cancer. All patients relapsed from or failed all other treatments, including prior treatment with capecitabine or 5-FU. For all doses of capecitabine in the Phase 1b NGC-Cap trial, exposure to 5-FU was greater and exposure to FBAL was lower with a better or similar side effect profile compared with monotherapy capecitabine. In addition, preliminary analysis of the efficacy data demonstrated early evidence of anti-tumor activity of capecitabine combined with PCS6422, which was assessed using RECIST 1.1 evaluations (Response Evaluation Criteria in Solid Tumors) by scans every eight weeks.

Key Efficacy Findings from Preliminary Analysis of NGC-Cap Phase 1b Clinical Trial (NCT04861987)

- In all evaluable patients receiving one dose of PCS6422 and seven days of capecitabine, PR or SD was observed in 66.7% (8 out of 12) of evaluable patients, including two with PR and six with SD. The length of PFS was approximately 5 to 11 months across these patients.
- At the MTD of 225 mg of capecitabine dosed twice daily after a single dose of PCS6422, all three evaluable patients (100%) had PFS with the time to progression being approximately 5 to 7 months.
- At the second highest dose of 150 mg capecitabine dosed twice daily after a single dose of PCS6422, 66.7% (2 out of 3) of evaluable patients had SD with the time to progression of approximately 3 to 7 months.
- These two dosage regimens will be further evaluated in the Phase 2 trial in breast cancer patients to determine the optimal dosage regimen for the pivotal trial.
- By comparison, in the capecitabine product label, 301 metastatic colorectal cancer patients treated with monotherapy capecitabine had an overall response rate of approximately 21% and the time to progression of approximately 4.5 months.

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 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 reach the 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 indication approvals 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. Processa is currently 1) starting to initiate sites for the Phase 2 study that will identify the optimal dosage regimen for Next Generation Capecitabine (PCS6422 and capecitabine to treat breast, metastatic colorectal, gastrointestinal, pancreatic and other cancers), 2) defining the design of the Next Generation Gemcitabine (PCS3117 to treat pancreatic, biliary, lung, ovarian, breast and other cancers) Phase 2 optimal dosage regimen study to discuss with FDA, and 3) defining the formulation and toxicology program for 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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