May 30, 2025

Processa Pharmaceuticals

Processa Pharmaceuticals Announces Presentation and Publication of Three Abstracts at 2025 ASCO Annual Meeting

HANOVER, Md., May 30, 2025 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical-stage pharmaceutical company focused on developing the next generation cancer therapies with improved efficacy and safety, today announced the acceptance of three abstracts for the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 30 to June 3, 2025, at McCormick Place in Chicago, Illinois. The abstracts highlight Processa's pipeline of Next Generation Cancer (NGC) drug candidates, including PCS6422 (NGC-Cap) and PCS11T (NGC-Iri), showcasing both preclinical and clinical advances.

Trials in Progress Poster Presentation and Abstract Publication

- **Abstract Title:** *Adaptive Designed Eniluracil + Capecitabine Phase 2 Trial in Advanced or Metastatic Breast Cancer Patients*
- **Abstract Number:** TPS1133 | **Poster Board Number:** 105b
- **Session Title:** Breast Cancer—Metastatic
- **Date & Time:** June 2, 2025 | 9:00 AM–12:00 PM CDT
  Dr. David Young, Founder and President of Research & Development at Processa, will be presenting an overview of Processa's ongoing Phase 2 adaptive design trial evaluating the safety and efficacy of PCS6422 (eniluracil) combined with capecitabine in patients with advanced or metastatic breast cancer. The study explores optimal dosing regimens and a personalized medicine approach to improve outcomes and tolerability.

Abstract Publications

1. **Abstract Title:** *Safety and Efficacy of Eniluracil + Capecitabine (6422 + Cap) in Phase 1b Trial*

Abstract Number: e15152

This online-only abstract provides data from the Phase 1b study that defined the Maximum Tolerated Dose (MTD) and Recommended Phase 2 Dose Range (RP2DR) for NGC-Cap (eniluracil + capecitabine or 6422 + Cap), highlighting its improved safety profile and anti-tumor activity compared to standard capecitabine.

2. **Abstract Title:** *Preclinical Project Optimus Dose Escalation of SN-38 Pro-Drug PCS11T*

Abstract Number: e15023

This online-only abstract outlines a Project Optimus-aligned approach to define the optimal therapeutic window of PCS11T, a tumor-targeted pro-drug of SN-38. PCS11T is designed to increase drug concentration in tumors while reducing systemic toxicity.

“These ASCO presentations and publications reflect the breadth of our oncology pipeline and the progress we’re making across multiple programs,” said Dr. David Young. “From our Phase 2 clinical program in metastatic breast cancer to preclinical innovations with PCS11T, we are leveraging our Regulatory Science Approach and deep oncology expertise to address critical unmet needs.”

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.

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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