

Processa Pharmaceuticals to Present PCS12852 Gastroparesis Results at the Digestive Disease Week 2023 Annual Meeting

- PCS12852 Shown to be Safe and Efficacious in Phase 2 Proof-of-Concept Trial in Gastroparesis Patients
- PCS12852 Improved Both Gastroparesis Symptom Scores and Gastric Emptying Rate

HANOVER, MD, April 28, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical-stage pharmaceutical company now focused on developing the next generation of chemotherapeutic drugs to improve the efficacy and safety for patients suffering from cancer, today announces it will be presenting data on the use of PCS12852 to treat gastroparesis patients at the annual Digestive Disease Week (DDW) conference held in Chicago's McCormick Place from May 6-9, 2023. PCS12852 is a Phase 2b-ready, very potent and very selective novel 5-HT4 agonist, for which the company is exploring partnerships and other options to advance the program.

The study, titled "PCS12852, A Novel 5-HT₄ Agonist Improves GCSI Symptom Scores and Gastric Emptying in Gastroparesis Patients," will be presented during the May 6th Research Forum Session, *AGA Gastroparesis and Small Intestinal Dysmotility* held from 2-3:30 PM CT. Sian Bigora, Pharm.D., Processa Pharmaceuticals' Chief Development and Regulatory Officer, will present the Phase 2a results on the improvement in symptom scores and gastric emptying rate in gastroparesis patients treated with PCS12852.

David Young, Pharm.D., Ph.D., Processa's President and CEO, commented, "We continue to see encouraging results with our drug development pipeline, and inclusion in the DDW conference as an oral presentation is important and continued validation for our Regulatory Science approach. Since the FDA-approved gastroparesis drugs have severe safety limitations, the fact that PCS12852 is ready to move to a Phase 2b trial given the positive safety and efficacy results in our proof-of-concept gastroparesis trial is a significant milestone. The Company is diligently exploring strategies to advance or monetize the program. We look forward to a robust discussion of the data throughout the DDW conference, and to providing continued updates to our shareholders."

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 Processa's 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 be providing better therapy options to cancer patients but also increase the probability of FDA approval for its Next Generation Chemotherapy (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 FDA-approved 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 drug development 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 approvals for indications across almost every division of 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. Currently under development are three next generation chemotherapy oncology treatments: Next Generation Capecitabine (PCS6422 and capecitabine to treat metastatic colorectal, gastrointestinal, breast, pancreatic, and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, lung, ovarian, breast, and other cancers), and 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.

For More Information:

Investors:

Bret Shapiro CORE IR ir@processapharma.com

Company Contact:

Patrick Lin (925) 683-3218 plin@processapharma.com



Source: Processa Pharmaceuticals, Inc.