July 1, 2025

Processa Pharmaceuticals Provides Portfolio and Business Update

- *Signed binding term sheet granting Intact Therapeutics an exclusive option to license PCS12852*
- *Continue enrolling patients in Phase 2 study of PCS6422*
- *Strengthened balance sheet with $7M capital infusion*

VERO BEACH, Fla., July 01, 2025 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical-stage pharmaceutical company developing next-generation cancer therapies, provides updates on its product pipeline, upcoming milestones and business activities.

“We are taking deliberate steps to focus our resources on programs with the highest potential for clinical success and commercial impact,” said Dr. David Young, President Research and Development at Processa. “Our approach continues to center on developing safer, more effective treatments for cancer while creating value through strategic business development and disciplined pipeline management.”

“Our NGC-Cap Phase 2 clinical trial in metastatic breast cancer is actively enrolling patients. We continue to anticipate sharing initial data in the second half of 2025,” said George Ng, Chief Executive Officer of Processa Pharmaceuticals. “The streamlining of our development pipeline, signing of strategic partnerships, and optimizing our capital allocation, enable us to make the necessary investments in our science in order to enhance shareholder value.”

Key Portfolio Updates:

- **PCS6422 (NGC-Cap):** PCS6422, Processa’s lead oncology asset in combination with capecitabine (NGC-Cap), is actively enrolling patients in a Phase 2 study for metastatic breast cancer. The program remains a top priority, with the remaining patients needed for the pre-planned interim analysis expected to be enrolled in the second half of 2025. The trial builds on compelling safety and efficacy signals observed in earlier studies, including improved tolerability and increased exposure to active cancer-killing metabolites.

- **PCS499:** Based on preliminary positive results in kidney disease and the FDA allowing surrogate endpoints to now be used in rare kidney diseases, Processa is currently designing a new adaptive pivotal PCS499 Phase III study to discuss with the FDA later this year. In addition, Processa is establishing a dedicated subsidiary to hold PCS499. The move is intended to enhance strategic flexibility in targeting capital raising and potential partnership exploration after meeting with the FDA.

- **PCS12852:** As previously announced, Processa has signed a binding term sheet with Intact Therapeutics, Inc. granting an exclusive option to license PCS12852 for gastroparesis and related gastrointestinal motility disorders. Under the terms, Processa

is eligible for up to $454 million in milestone payments, a 12% royalty on future sales, and a 3.5% equity stake in Intact. The partnership represents a strategic monetization of non-core assets while maintaining upside potential.

- **PCS11T:** PCS11T is Processa's preclinical oncology asset based on the active metabolite of irinotecan. The company continues to define and explore preclinical and clinical development strategies as well as opportunities to support future development.

- **PCS3117:** After determining that the time and cost required to advance PCS3117 to a meaningful milestone would be too high, Processa has terminated the license agreement for PCS3117 and returning the rights to the original licensor.

Commitment to Shareholder Value

These portfolio changes align with Processa's strategic intent to focus on oncology assets with strong differentiation, scientific rationale, commercial opportunity and clear regulatory pathways. The company believes this will optimize our human and capital resources, expedite the unlocking of hidden asset value through partnerships, and position the organization to deliver long-term shareholder returns.

Investor Webinar

Processa CEO George Ng will participate in a live investor webinar on Wednesday, July 9, 2025, at 4:15 p.m. ET to discuss the company's strategic pipeline realignment and value-creating milestones.

To register for the free webinar, please visit:
https://www.redchip.com/webinar/PCSA/85765532754

Questions can be pre-submitted to PCSA@redchip.com or online during the live event.

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. In addition to its core oncology programs, Processa is actively pursuing strategic partnerships for non-oncology assets to unlock additional value

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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